CKD/ESRD MEDICATION MEASURES FOR QUALITY IMPROVEMENT ORGANIZATIONS AND ESRD NETWORKS

- FINAL REPORT-

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EXECUTIVE SUMMARY

On December 8, 2003, Congress enacted the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), which offers a new prescription drug benefit to eligible Medicare beneficiaries. Section 109 (b) of the MMA amended Section 1154(a) of the Social Security Act to give Quality Improvement Organizations (QIOs) authority to provide quality improvement assistance pertaining to prescription drug therapy to Medicare Advantage plans and prescription drug sponsors offering prescription drug plans under Part D. In September 2005, the Centers for Medicare & Medicaid Services (CMS) contracted with BearingPoint to develop a set of candidate medication measures intended for use by QIOs and End Stage Renal Disease (ESRD) Networks to improve quality and patient safety in providing care to the Medicare-eligible population with chronic kidney disease (CKD) and ESRD.

Following contract award, BearingPoint developed an initial set of candidate measures for ESRD and CKD, approved by CMS on January 23, 2006. This set of measures was discussed at a Technical Expert Panel (TEP) Meeting later that same month, revised based on TEP feedback, and submitted to CMS on April 14, 2006. After CMS's review, revision, and approval, the candidate measures were posted on a Stakeholder Web site from April 21 to May 22, 2006 to gather feedback from stakeholders, including QIOs, ESRD Networks, large dialysis organizations (LDOs), and other professional organizations. The ESRD/CKD medication measures were revised again based on stakeholder comments and submitted to CMS in July 2006. In preparation for the Stakeholders Meeting and Second TEP, CMS and BearingPoint further revised the measures in September 2006. Then, on October 10, 2006, the team held a Stakeholders Meeting to inform stakeholders about the progress of the CKD/ESRD candidate measures. The second TEP Meeting was held the next day to allow TEP members an opportunity to further discuss modifications to the proposed measures based on comments received the previous day. BearingPoint incorporated TEP comments and feedback and submitted the final proposed candidate measures to CMS in December 2006.

Following CMS approval, the team developed draft technical specifications for the ESRD/CKD medication Measure Sets 1 and 2, in February and May 2007, respectively. Measure Set 1 included measures that could be calculated using Part D enrollment and drug claims data as well as data from the Renal Management Information System (REMIS)/Standard Information Management System (SIMS) to identify Part D enrollees with ESRD (dialysis) and CKD beneficiaries with a functioning transplant. Measure Set 2 included measures that required additional data that were not available to the team. This data included International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnosis codes, Current Procedural Terminology (CPT) codes, and Healthcare Common Procedure Coding System Level II (HCPCS) codes for drugs not covered by Part D. The original scope of work specified that BearingPoint conduct formative testing of the measures in Measure Set 1 using data provided by Medicare Advantage Prescription Drug Plans (MA-PDs) and Prescription Drug Plans (PDPs). In March 2007, given the challenges in obtaining plans' data, CMS halted the formative test of the measures in Measure Set 1.

The constraints of using drug proxies to identify the CKD population constituted one of several limitations of this project. Drug proxies were used to identify the CKD population although drug proxies cannot identify people with CKD Stages 1 and 2, nor distinguish between Stages 3 through 5. Because the TEP felt that certain disease specific and monitoring measures were important to consider, measures were developed that also required data in addition to SIMS and Part D data: ICD-9-CM diagnosis codes, CPT procedure codes, and HCPCS drug codes for drugs not covered by Part D. Other limitations included not testing and refining the algorithms using Part D and other data due to the prohibition from obtaining Part D data from CMS and the difficulties in obtaining data directly from Part D plans.

Notwithstanding these limitations, CMS, BearingPoint, and the TEP succeeded in developing an initial set of medication measures for the CKD and ESRD populations. QIOs and ESRD Networks could choose to test and further develop these measures to assist PDPs and MA-PDs in identifying potential areas of quality improvement for these special populations. This initial set of ESRD/CKD medication measures covers:

- Common drug safety concerns, such as potential drug-drug interactions, drugs requiring appropriate dosing, and drugs to be avoided
- Use of the Part D benefit by both ESRD and CKD populations
- Concerns about the use of angiotensin II receptor blockers (ARBs) and angiotensin-converting enzyme inhibitors (ACEIs) to regulate blood pressure in the diabetic CKD population
- Use of bisphosphonate therapy, potassium-sparing diuretic therapy, and antihypertensive therapy in the CKD population.

With the potential availability of additional data such as ICD-9-CM diagnosis codes, CPT procedure codes for therapeutic monitoring, and HCPCS codes for drugs not covered by Part D, measures were developed to examine the use of:

- ACEIs and ARBs in the hypertensive, diabetic CKD population including beneficiaries in all stages of CKD
- More than once-per-day dosing of antihypertensive drugs
- Thiazides without loop diuretics
- Anemia evaluation in patients treated with erythropoiesis stimulating agents (ESA)
- Vitamin D sterol therapy monitoring.

The specifications provide a baseline for subsequent refinement of the methods and development of medication measures in the future. The Executive Summary Table shows the quality measures for which initial algorithms were developed under this contract.

Executive Summary Table
CKD/ESRD Medication Measures for Quality Improvement Organizations (QIOs) and End Stage Renal Disease (ESRD) Networks

Measure Set 1. CKD/ESRD Quality Measures Using Part D Enrollment, Part D Claims, and SIMS Data

Domain 1: Patient Safety Measures	Count
Drug-Drug Interactions	
1.1a1 Percentage of ESRD (dialysis) patients with ≥ 2 drugs having the potential to interact	1
1.1a2 Among ESRD (dialysis) patients with ≥1 object or precipitant drug, percentage with ≥ 2 drugs having the potential to interact	2
1.1b1 Percentage of CKD (including transplant) beneficiaries with ≥ 2 drugs having the potential to interact	3
1.1b2 Among CKD (including transplant) beneficiaries with ≥ 1 object or precipitant drug, percentage with ≥ 2 drugs having the potential to interact	4
Drugs Requiring Caution	
1.2a Percentage of ESRD (dialysis) patients with drugs to be avoided	5
1.2b Percentage of CKD (including transplant) beneficiaries with drugs requiring appropriate dosing	6
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Generic Utilization Ratios	
2.1a Percentage of generic utilization (absolute) for ESRD (dialysis) patients	7
2.1b Percentage of generic utilization (absolute) for CKD (including transplant) beneficiaries	8
2.2a Percentage of generic utilization (adjusted) for ESRD (dialysis) patients	9
2.2b Percentage of generic utilization (adjusted) for CKD (including transplant) beneficiaries	10
Domain 3: Disease Specific Therapy Measures	
CKD Diabetes Mellitus and ACEI/ARB Therapy	
3.1 Percentage of CKD (including transplant) beneficiaries with diabetes mellitus (DM) with ≥ 90 days supply of angiotensin converting enzyme inhibitors (ACEIs) and/or angiotensin II receptor blockers (ARBs) This is also classified into the following: Percentage of diabetic CKD (including transplant) beneficiaries with:	11
3.1a ACEI only	12
3.1b ARB only	13
3.1c ACEI switching to ARB only	14
3.1d ARB switching to ACEI only	15
3.1e Multiple switches between ARB and ACEI	16
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3.4 Percentage of CKD (including transplant) beneficiaries with ≥ 90 days supply of antihypertensive therapy (excluding potassium-sparing diuretics)	22
CKD and Potassium-Sparing Diuretic Therapy	
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Executive Summary Table
CKD/ESRD Medication Measures for Quality Improvement Organizations (QIOs) and End Stage Renal Disease (ESRD) Networks

Measure Set 2. CKD/ESRD Quality Measures Using Additional Data*

Domain 3: Disease Specific Therapy Measures	Count
CKD Diabetes Mellitus and ACEI/ARB Therapy	
3.1** Percentage of CKD (Stages 1-5 including transplant) beneficiaries with diabetes mellitus (DM) and hypertension (HTN) with ≥ 90 days supply of ACEI and/or ARB drugs	1
This is also classified into the following: Percentage of diabetic hypertensive CKD (Stages 1-5 including transplant) beneficiaries with:	
3.1a ACEI only	2
3.1b ARB only	3
3.1c ACEI switching to ARB only	4
3.1d ARB switching to ACEI only	5
3.1e Multiple switches between ARB and ACEI	6
CKD and Antihypertensive Therapy	
3.5 Percentage of CKD (Stages 1-3 including transplant) hypertensive beneficiaries with a more than once-a-day dosage regimen of antihypertensive drugs	7
CKD and Thiazide Therapy	
3.7 Percentage of CKD (Stages 4-5 including transplant) beneficiaries with ≥ 90 days supply of thiazide diuretics, but no loop diuretics	8
Domain 4: Therapeutic Monitoring Measures	
CKD and Anemia Evaluation	
4.1 Percentage of CKD (Stages 3-5 including transplant) beneficiaries with an anemia evaluation prior to treatment with erythropoiesis stimulating agents (ESA)	9
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*Note: Shading indicates measures requiring additional datasets.
** Measure 3.1 is also included in Measure Set 1 because the original definition used drug proxies to identify CKD and diabetes. This measure was further refined using ICD-9-CM codes to identify diabetic hypertensive CKD (Stages 1-5) beneficiaries.

1. INTRODUCTION

On December 8, 2003, Congress enacted the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), which offers a new prescription drug benefit to eligible Medicare beneficiaries. Section 109 (b) of the MMA amended Section 1154(a) of the Social Security Act to give Quality Improvement Organizations (QIOs) authority to provide quality improvement assistance pertaining to prescription drug therapy to Medicare Advantage plans and prescription drug sponsors offering prescription drug plans under Part D.

In September 2005, the Centers for Medicare & Medicaid Services (CMS) contracted with BearingPoint to develop a set of candidate medication measures. CMS intends the measures to be used by QIOs and End Stage Renal Disease (ESRD) Networks for the purposes of quality improvement and patient safety in providing care to the Medicare-eligible population with chronic kidney disease (CKD) and ESRD.

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Plans (MA-PDs) and Prescription Drug Plans (PDPs). In March 2007, given the challenges in obtaining plans' data, CMS advised BearingPoint to halt the formative test of the measures in Measure Set 1.

This report describes the process used to identify, prioritize, and develop the ESRD/CKD medication measures. Section 2 provides the methods used to develop and refine the draft candidate measures. Section 3 summarizes BearingPoint's preliminary efforts in obtaining data to conduct formative testing. Section 4 briefly discusses preparing the Measure Set 1 measure information forms and measure justification forms for the CMS Measure Management Systems. Section 5 provides a summary of the project. Finally, Section 6 lists the appendices referenced in this report. These appendices are provided as separate documents.

2. MEDICATION MEASURE DEVELOPMENT

2.1. DEVELOPMENT OF INITIAL SET OF DRAFT CANDIDATE MEASURES

2.1.1. Methods

CMS tasked BearingPoint with developing candidate medication measures for CKD/ESRD populations based on Medicare Part D and other available claims data. The initial domains for the measures were:

- Prescribing
  - Drug-drug interactions
  - Use of avoidable drugs in the CKD/ESRD population
  - Use of selected medications within certain therapeutic categories.
- Disease-specific therapy
  - Drug-disease interactions
  - Therapeutic monitoring associated with specific drug utilization
  - Generic prescribing ratios
  - Appropriateness of therapy measures
  - Appropriate prescribing and drug regimen for specified disease states.

The contract's scope of work (SOW) specified that prior to developing the measures, the BearingPoint team: 1) conduct a thorough review of the literature, and 2) determine if existing clinical practice guidelines were available to use to derive the measures.

CMS intended that the measures be calculable to the extent possible using only Part D enrollment and Part D claims data. Appendix A shows the data elements in Part D claims data known as Prescription Drug Event (PDE) data. As the preliminary candidate measures were identified based on the review of literature and existing clinical practice guidelines, it became clear that additional data would be necessary to identify Part D enrollees with ESRD or CKD and to calculate the measures.

To clearly identify Part D enrollees with ESRD, the Renal Management Information System (REMIS)/Standard Information Management System (SIMS),[1] in conjunction with Part D enrollment data, would be necessary to identify ESRD patients on dialysis and those with a functioning transplant.

[1] SIMS is a component of the Consolidated Renal Operations in a Web-enabled Network (CROWN), an integrated information management system for the ESRD program. Another component is the Renal Management Information System (REMIS), which calculates Medicare coverage periods for ESRD patients and serves as the primary mechanism to store and access ESRD patient and facility information in the ESRD Program Management and Medical Information System database (ESRD PMMIS). In July 2003 REMIS replaced the Renal Beneficiary and Utilization System (REBUS), successor to PMMIS. REMIS tracks the ESRD population for both Medicare and non-Medicare patients from other government healthcare programs such as Veterans Affairs. REMIS includes a link to the Medicare Enrollment Database (EDB) and operational interface to SIMS providing secure, role-based access to current ESRD patient and facility data. REMIS also includes sophisticated data quality problem resolution support.

Part D enrollees with CKD were more challenging to identify. Ideally, a laboratory result documenting glomerular filtration rate (GFR) would be necessary to classify an enrollee as having CKD as well as to determine the stage of CKD:

- Stage 1—Kidney damage with normal or above normal GFR ≥ 90 (ml./min/1.73m^2)
- Stage 2—Kidney damage with mild decrease of GFR (range 60-89).
- Stage 3—Kidney damage with moderate decrease of GFR (range 30-59)
- Stage 4—Kidney damage with severe decrease of GFR (range 15-29)
- Stage 5—Kidney failure with GFR < 15, or dialysis.

Medical records include these laboratory results but are generally paper records, not available electronically. The laboratory results are not included in electronic administrative claims data such as hospital inpatient, hospital outpatient, or physician claims data. New ICD-9-CM codes were introduced in October 2005 to identify CKD stage, but the reliability and validity of the actual use of these codes has not been established. As a result, Part D enrollees with CKD Stages 3 through 5 were identified using drug proxies (chronic use of a phosphate binder such as calcium acetate, sevelamer hydrochloride, lanthanum carbonate, or oral vitamin D sterols such as calcitriol, paricalcitol, doxercalciferol, or dihydrotachysterol). There were no drug proxies to define enrollees with CKD Stages 1 and 2, nor could drug proxies be used to differentiate Stages 3 through 5.

For each potential measure identified for this project, the team prepared a measure summary form that included the following information:

- Name of measure
- Potential use of measure (e.g., quality improvement, cost effectiveness, public reporting)
- Measure source
- Literature citation
- Evidence based or opinion based
- Purpose(s) of the measure
- Type of measure
- Clinical or other domain
- Measure setting
- Data sources required
- Extent of prior use
- Importance/relevance
- Scientific soundness
- Feasibility.

BearingPoint compiled the measure summary forms for each draft candidate measure into the Candidate Measure Report, submitted to CMS on January 23, 2006. The document prioritized the order in which the measures could be further developed into CKD/ESRD medication

measures, assigning higher weights to those that were evidence based and those derived from clinical trials and more scientifically rigorous studies. The Candidate Measure Report included a reference list of the journal articles and studies reviewed, additional searches and data analysis conducted to identify measures, and any other information that was helpful in the identification, prioritization, and development of the measures.

2.1.2. Draft Measures

Table 1 presents the initial set of candidate measures with their respective denominator and numerator statements.

Table 1. Proposed Medication Measures for End Stage Renal Disease (ESRD) and Chronic Kidney Disease (CKD) (01/23/06)

Measure Description	Denominator and Numerator Statements
Prescribing	
Prescribing #1: Prevalence of the number of Chronic Kidney Disease (CKD) beneficiaries and/or End Stage Renal Disease (ESRD) patients who had two or more Prescription Drug Event (PDE) claims for drugs with the potential to interact	Denominator Statement: CKD beneficiaries and/or ESRD patients with PDE claims for drugs during the measurement period Numerator Statement: CKD beneficiaries and/or ESRD patients in the denominator with PDE claims for ≥1 Drug-Drug Interactions (DDI) during the measurement period
Prescribing #2: Prevalence of Drugs to Avoid (DTA) in CKD beneficiaries and/or ESRD patients	Denominator Statement: CKD beneficiaries and/or ESRD patients who had PDE claims during the measurement period Numerator Statement: CKD beneficiaries and/or ESRD patients in the denominator with ≥1 DTA in PDE claims during the measurement period
Prescribing #3: Prevalence of lipid lowering drugs (statins or fibrates) among CKD beneficiaries and/or ESRD patients	Denominator Statement: CKD beneficiary and /or ESRD patients with PDE claims during measurement period Numerator Statement: Number of CKD beneficiaries and/or ESRD patients in the denominator who had PDE claims for lipid lowering drugs during the measurement period
Prescribing #4: Prevalence of combined use of HMG CoA Reductase Inhibitors (or statins) and fibrates among CKD beneficiaries and /or ESRD patients	Denominator Statement: CKD beneficiaries and/or ESRD patients with PDE claims during measurement period Numerator Statement: Number of CKD beneficiaries and /or ESRD patients in the denominator who had PDE claims for a statin and a fibrate drug during the measurement period
Prescribing #5: Prevalence of zero antihypertensive agents among CKD beneficiaries and/or ESRD patients	Denominator Statement: All CKD beneficiaries and/or ESRD patients with PDE claims during measurement period Numerator Statement: Number of CKD beneficiaries and/or ESRD patients in the denominator who had no PDE claims for any anti-hypertensive agents during the measurement period
Prescribing #6: Prevalence of monotherapy in hypertensive treatment among CKD beneficiaries and/or ESRD patients	Denominator Statement: CKD beneficiaries and/or ESRD patients with PDE claims during measurement period Numerator Statement: CKD beneficiaries and/or ESRD patients in the denominator who had PDE claims for one (1) antihypertensive drugs during the measurement period

Table 1. Proposed Medication Measures for End Stage Renal Disease (ESRD) and Chronic Kidney Disease (CKD) (01/23/06)	
Measure Description	**Denominator and Numerator Statements**
Prescribing #7: Prevalence of using ≥2 antihypertensive agent among CKD beneficiaries and/or ESRD patients	Denominator Statement: CKD beneficiaries and/or ESRD patients with PDE claims during measurement period Numerator Statement: CKD beneficiaries and/or ESRD patients in the denominator who had PDE claims for ≥2 antihypertensive drugs during the measurement period
Prescribing #8: Prevalence of generic utilization among PDE claims for CKD beneficiaries and/or ESRD patients	Denominator Statement: All PDE claims for CKD beneficiaries and/or ESRD patients during measurement period Numerator Statement: Number of PDE or claims not allowed for generic formulation (code 1) dispensing for CKD beneficiaries and/or ESRD patients during the measurement period
Disease-Specific Therapy	
Disease-Specific Therapy #1 Prevalence of epoetin or darbepoetin among CKD beneficiaries and/or ESRD patients	Denominator Statement: All CKD beneficiaries and/or ESRD patients with PDE claims during the measurement period Numerator Statement: Number of CKD beneficiaries and/or ESRD patients in the denominator with PDE claims for epoetin or darbepoetin during the measurement period
Disease-Specific Therapy #2 Prevalence of therapeutic monitoring among CKD beneficiaries and/or ESRD patients who had PDE claims for epoetin or darbepoetin	Denominator Statement: All CKD beneficiaries and/or ESRD patients with PDE claims for epoetin or its analogue during the measurement period Numerator Statement: Number of CKD beneficiaries and/or ESRD patients in the denominator who had documented anemia work up or Hgb or Hct test during the measurement period
Disease-Specific Therapy #3 Prevalence of PDE claims for oral calcitriol, doxercalciferol or paricalcitol among CKD beneficiaries and/or ESRD patients	Denominator Statement: All CKD beneficiaries and/or ESRD patients with PDE claims during the measurement period Numerator Statement: Number of CKD beneficiaries and/or ESRD patients in the denominator with PDE claims for calcitriol, doxercalcitriol or paricalcitol during the measurement period
Disease-Specific Therapy #4 Prevalence of PDE claims for bisphosphonates among CKD beneficiaries and/or ESRD patients	Denominator Statement: All male CKD beneficiaries and/or ESRD patients with PDE claims for Part D covered drugs during the measurement period Numerator Statement: Number of male CKD beneficiaries and/or ESRD patients in the denominator with PDE claims for any one of the bisphosphonates during the measurement period
Appropriateness of Therapy	
Appropriateness of Therapy #1 Appropriate dosing of erythropoietin (EPO) among CKD beneficiaries and/or ESRD patients	Denominator Statement: All CKD beneficiaries and/or ESRD patients with PDE claims for epoetin or darbepoetin during measurement period Numerator Statement: Number of CKD beneficiaries and/or ESRD patients in the denominator with PDE claims for epoetin ≥ monthly dose of 500,000 iu (or ≥1500mcg a month for darbepoetin) during the measurement period

Table 1. Proposed Medication Measures for End Stage Renal Disease (ESRD) and Chronic Kidney Disease (CKD) (01/23/06)	
Measure Description	**Denominator and Numerator Statements**
Appropriateness of Therapy #2 Appropriate Dosing of Selected Drugs among CKD beneficiaries and/or ESRD patients	Denominator Statement: All CKD beneficiaries/ESRD patients with ≥ 1 unique PDE claims for drugs during measurement period Numerator Statement: Number of CKD beneficiaries/ESRD patients in the denominator with ≥ 1 PDE claims for one of the Selected Drugs that exceeded the maximum daily dose for CKD during the measurement period
Appropriateness of Therapy #3 Prevalence of iron supplement among CKD beneficiaries and/or ESRD patients	Denominator Statement: All CKD beneficiaries/ESRD patients with PDE claims during measurement period Numerator Statement: Number of CKD beneficiaries/ESRD patients in the denominator with ≥1 PDE claims for iron supplement during the measurement period
Appropriateness of Therapy #4 Prevalence of CKD beneficiaries and/or ESRD patients potentially eligible for enrollment in medication therapy management program (MTMP)	Denominator Statement: Total CKD beneficiaries and/or ESRD patients with PDE claims during measurement period Numerator Statement: Total number of CKD beneficiaries and/or ESRD patients each with PDE claims ≥ $4,000 in ingredient costs during measurement period

2.2. First Technical Expert Panel Meeting

2.2.1. Purpose and Methods

The purpose of the first TEP was to assist the BearingPoint team in the identification, prioritization, and development of CKD/ESRD medication measures for patients with CKD by CKD stage of severity and ESRD. In consultation with CMS, BearingPoint recruited and assembled a TEP to provide input on the first draft of proposed candidate medication measures for CKD beneficiaries and ESRD patients. The TEP members consisted of 13 non-government employed individuals and two government-employed individuals; each member is considered a nationally recognized expert with experience in measure development, quality improvement, ESRD and/or Dialysis Networks, and other selected complementary areas based on the expertise needed to evaluate the proposed candidate measures.

The primary objectives of the TEP were to:

- Discuss the proposed candidate measures and identify other possible measures for further development, and
- Assist BearingPoint with amending and refining the list of proposed candidate quality measures for QIO and ESRD Network quality improvement activities.

Ultimately, the proposed candidate measures, after refinement and approval from CMS, may provide the basis for QIOs and ESRD Networks to assess quality improvement, interventions, and patient safety.

2.2.1.1. Identifying TEP Members

To assemble the panel of experts, BearingPoint began by identifying the general types of expertise required, based on the candidate measure domains CMS proposed. Then, working closely with CMS, the project team identified individuals in each area who could provide insight on content, method, data management, and quality improvement. CMS narrowed the list and the project team invited the selected individuals to serve on the panel. Appendix B shows a list of TEP members and their affiliations.

Each CMS-approved candidate measure was assigned to one of the three workgroups:

- Workgroup 1: Drug-Drug Interactions (DDI), Adverse Drug Reactions (ADR), and Appropriate Dosing
- Workgroup 2: Cardiovascular Disease (CVD) in ESRD and CKD
- Workgroup 3: Therapeutic Monitoring and Drug Utilization.

To provide a variety of perspectives and ensure that each workgroup included the requisite knowledge and expertise to evaluate the measures, each workgroup included a subject matter expert (e.g., a physician, pharamacoeconomist, or pharmacist), a data claims expert, a quality improvement expert (e.g., someone who has worked directly or as a consultant for QIOs), an ESRD Network or Dialysis Network expert, a government official or individual with quality measurement development and/or implementation experience, and a patient advocate.[2] The workgroups and measures assignments can be found in Appendix C.

2.2.1.2. Meeting Agenda and Organization

Prior to the meeting, BearingPoint conducted telephone conferences with the TEP members and workgroup facilitators to discuss the purpose of the TEP, each member's role and responsibilities, the expectations for TEP members (both prior to and during the meeting), and the pre-meeting materials. In addition, panelists were sent the Candidate Measure Report, which contained detailed descriptions of BearingPoint's proposed candidate medication measures, and an individual evaluation form for each measure assigned to that panelist's workgroup.[3] The individual evaluation forms were created based on the Evaluation Criteria Definitions proposed by the Health Services Advisory Group's (HSAG) Measures Management System (MMS) protocol. Appendix D shows a sample of the individual evaluation forms and the Evaluation Criteria Definitions.

The two-day meeting was held on January 26 and 27, 2006 in Baltimore, MD. The meeting started with a series of presentations about the project objectives and expectations of the TEP, the Medicare Prescription Drug Benefit Program (Part D), applicability of the measures to QIOs and ESRD Networks, United States Renal Data System (USRDS) data sets, and the Part D data set. Appendix E includes a copy of the agenda. After the presentations, the TEP members

[2] In some cases, certain individuals had expertise in more one area.
[3] Most panelists received the Candidate Measures Report for the TEP and individual evaluation forms two days prior to the TEP. However, due to mailing delays and panelists' schedules, some panelists did not obtain the finalized documents until immediately preceding the start of the TEP.

separated into their workgroups and reported their individual recommendations to CMS and the remaining workgroup members as part of a roundtable discussion. Each group was facilitated by a TEP member and supported by two BearingPoint project staff – a key technical staff person and a note taker.

During the workgroup sessions, TEP members were asked to evaluate five to six measures and develop a consensus on whether to accept the measure as written, accept with modification, or delete. The workgroups also proposed new measures and defined the new measure name, numerator, denominator, and data element(s) required for calculation. After discussing each measure, group facilitators captured the workgroup's recommendations on the Group Evaluation Form (Appendix F). The results were presented for additional debate and refinement to an audience consisting of CMS and BearingPoint staff, as well as remaining TEP members, during roundtable discussions at the conclusion of each day.

2.2.2. Summary of TEP Findings

Highlights of the recommendations made in the Group Evaluation Forms and during the roundtable discussions are provided below. A more detailed description of the TEP proceedings and findings was included in the TEP Summary Report, submitted to CMS on March 26, 2006. General comments about the measures included:

- The challenges of standardizing the definitions for CKD and ESRD populations with the available data. The Part D claims data do not include ICD-9-CM diagnosis codes; therefore, relying on drug proxies, such as those proposed, would overlook a significant number of CKD beneficiaries.
- Identification of the National Kidney Foundation's (NKF) Kidney Disease Outcomes Quality Initiative (K/DOQI) guidelines as the most important reference for developing and refining all measures.
- As an alternative to Medicare Parts A (hospital inpatient) and B (hospital outpatient and physician) data, need to identify other possible benchmarks (e.g., Modification of Diet in Renal Disease [MDRD], eGFR, GFR calculated from serum creatinine [SCr] vs. reported values of GFR and SCr levels).
- Usefulness of Form 2728 or the SIMS database, which has a complete registry of ESRD patients.

Table 2 summarizes the TEP's recommendations for the measures assigned to Workgroups 1, 2, and 3.

Table 2. Revisions to the Proposed Measures based on Technical Expert Panel (TEP) Comments

Measure	Comments
Workgroup 1: Drug-Drug Interactions (DDI), Adverse Drug Reactions (ADR), Appropriate Dosing	
• Prevalence of one or more potential drug-drug interactions (DDI)	
- ESRD population	Accept with modification
- CKD population	Accept with modification
• Prevalence of one or more drugs to avoid (DTA)	
- ESRD population	Accept with modification
- CKD population	Delete
• Appropriate dosing of epoetin (EPO)	
- ESRD population	Delete
- CKD population	Delete
• Appropriate dosing of selected drugs	
- ESRD population	Accept with modification
- CKD population	Delete
• Appropriate therapy with iron supplement	
- ESRD population	Delete
- CKD population	Delete
• Appropriate monitoring of iron status in CKD beneficiaries receiving iron supplementation	*New Measure*
• Appropriate prescribing of angiotensin converting enzyme inhibitors (ACEI)/ angiotensin II receptor blockers (ARB) in CKD beneficiaries	*New Measure*
• Appropriate monitoring of CKD	*New Measure*
Workgroup 2: Cardiovascular Disease (CVD) in ESRD and CKD	
• Prevalence of lipid lowering agents (LLA)	
- ESRD population	Delete
- CKD population	Accept with modification
• Prevalence of combined use of statins and fibrates	
- ESRD population	Delete
- CKD population	Delete
• Prevalence of no antihypertensive agents	
- ESRD population	Delete
- CKD population	Delete
• Prevalence of mono antihypertensive therapy	
- ESRD population	Delete
- CKD population	Delete
• Prevalence of at least 2 antihypertensive agents	
- ESRD population	Delete
- CKD population	Delete
• Prevalence of LLA in CVD among ESRD patients	*New Measure*
• Prevalence of any antihypertensive agents among CKD beneficiaries	*New Measure*
• Prevalence of ACEI/ARB prescription for hypertensive treatment among CKD beneficiaries	*New Measure*
• Prevalence of dihydropyridine calcium channel blocker (CCB) among CKD beneficiaries not receiving ACEI/ARB	*New Measure*
• Patients receiving antihypertensive agents requiring more than once daily administration	*New Measure*
• Influenza vaccine in dialysis patients	*New Measure*
• Thiazide use in CKD stages 4 and 5	*New Measure*
• Use of potassium-sparing diuretics in CKD patients on ACEI/ARB	*New Measure*

Table 2. Revisions to the Proposed Measures based on Technical Expert Panel (TEP) Comments	
Measure	**Comments**
Workgroup 3: Therapeutic Monitoring and Drug Utilization	
• Generic utilization ratio	
- ESRD population	Accept with modification
- CKD population	Accept with modification
• Prevalence of epoetin (EPO) and its analogue	
- ESRD population	Delete
- CKD population	Accept with modification
• Prevalence of therapeutic monitoring – anemia workup or hematocrit/hemoglobin prior to EPO	
- ESRD population	Delete
- CKD population	Accept with modification
• Prevalence of vitamin D therapy	
- ESRD population	Accept with modification
- CKD population	Delete
• Prevalence of bisphosphonates therapy	
- ESRD population	Delete
- CKD population	Accept with modification
• Prevalence of CKD beneficiaries and/or ESRD patients eligible for medication therapy management programs (MTMP)	
- ESRD population	Delete
- CKD population	Delete
• Prevalence of ESRD patients with no Part D claims in the measurement period	*New Measure*
• Prevalence of CKD beneficiaries with no Part D claims in the measurement period	*New Measure*

2.2.3. Revised Measures

Based on the results from the meeting, as well as follow-up conversations with TEP members, BearingPoint refined and amended the draft measures and submitted a revised Measure Input Document (MID) to CMS for review and approval. Table 3 summarizes the revised ESRD/CKD medication measures as of April 14, 2006, including the measure name, denominator statement, and numerator statement.

Table 3. Proposed Medication Measures for End Stage Renal Disease (ESRD) and Chronic Kidney Disease (CKD) (04/14/06)	
Measure Description	**Denominator and Numerator Statements**
Patient Safety Measures	
Patient Safety #1 Percentage of CKD beneficiaries and ESRD patients who had two or more drugs with the potential for a drug-drug interaction (DDI)	Denominator Statement: CKD beneficiaries and ESRD patients with Prescription Drug Event (PDE) claims for >1 unique drugs during the measurement period Numerator Statement: CKD beneficiaries and ESRD patients in the denominator with ≥1 potential DDI in PDE claims during measurement period
Patient Safety #2 Percentage of CKD (Stages 3-5 pre-dialysis) beneficiaries with Drugs Requiring Caution (DRC)	Denominator Statement: CKD beneficiaries with PDE claims for drugs during the measurement period Numerator Statement: CKD beneficiaries in the denominator with ≥1 DRC in PDE claims during measurement period

Table 3. Proposed Medication Measures for End Stage Renal Disease (ESRD) and Chronic Kidney Disease (CKD) (04/14/06)	
Measure Description	**Denominator and Numerator Statements**
Patient Safety #3 Percentage of ESRD (dialysis) patients with Drugs Requiring Caution (DRC)	Denominator Statement: ESRD patients with PDE claims for drugs during the measurement period Numerator Statement: ESRD patients in the denominator with ≥1 DRC in PDE medical claims during measurement period
Pharmacoeconomic Measures	
Pharmacoeconomics #1 Generic utilization ratio among drug claims for CKD (Stages 3-5 pre-dialysis) beneficiaries	Denominator Statement: All PDE claims for Part D covered drugs for CKD beneficiaries during the measurement period Numerator Statement: PDE claims for CKD beneficiaries in the denominator that are for generic formulations (use generic NDCs) during the measurement period
Pharmacoeconomics #2 Generic utilization ratio among drug claims for ESRD (dialysis) patients	Denominator Statement: All PDE claims for Part D covered drugs for ESRD patients during the measurement period Numerator Statement: PDE claims for ESRD patients in the denominator that are for generic formulations (use generic NDCs) during measurement period
Disease Specific Therapy Measures	
Disease Specific Therapy #1 Percentage of claims for angiotensin converting enzyme inhibitors (ACEI)/ angiotensin receptor blockers (ARB) among CKD beneficiaries (Stages 3-5 pre-dialysis) with diabetes mellitus (DM)	Denominator Statement: Diabetic CKD beneficiaries with PDE claims for Part D covered drugs during the measurement period Numerator Statement: CKD beneficiaries in the denominator with PDE claims for ACEI/ARB during measurement period
Disease Specific Therapy #2 Percentage of claims for calcitriol, doxercalciferol, or paricalcitol among CKD beneficiaries (Stages 4-5 pre- dialysis) and ESRD (dialysis) patients	Denominator Statement #2a: CKD stages 4-5 (pre-dialysis) including pediatrics (<18 years of age) beneficiaries with ≥1 PDE claims for Part D drugs during the measurement period Numerator Statement #2a: CKD beneficiaries in the denominator with PDE claims for an oral formulation of active vitamin D sterol during measurement period Denominator Statement #2b: ESRD patients including pediatrics (<18 years of age) with medical claims during the measurement period Numerator Statement #2b: ESRD patients in the denominator with medical claims for intravenous active vitamin D sterol therapy during measurement period
Disease Specific Therapy #3 Percentage of CKD beneficiaries (Stages 3-5 pre-dialysis) with claims for bisphosphonates who had been tested for serum PTH	Denominator Statement: CKD beneficiaries (Stages 3-5 pre-dialysis) with PDE claims for bisphosphonte during the measurement period Numerator Statement: CKD beneficiaries in the denominator who had at least one claim for serum PTH within 1 year prior to PDE claims for bisphosphonate during measurement period

Table 3. Proposed Medication Measures for End Stage Renal Disease (ESRD) and Chronic Kidney Disease (CKD) (04/14/06)	
Measure Description	**Denominator and Numerator Statements**
Disease Specific Therapy #4 ESRD (dialysis) patients with ≤1 Part D covered drug in claims	Denominator Statement: ESRD patients eligible for Part D benefits during the measurement period Numerator Statement: ESRD patients in the denominator with ≤1 Part D covered drug in PDE claims during measurement period
Disease Specific Therapy #5 CKD (Stages 3-5 pre-dialysis) beneficiaries with ≤1 Part D covered drug in claims	Denominator Statement: CKD beneficiaries eligible for Part D benefits during the measurement period Numerator Statement: CKD beneficiaries in the denominator with ≤1 Part D covered drug in PDE claims during measurement period
Disease Specific Therapy #6 Percentage of CKD beneficiaries and ESRD (dialysis) patients with lipid lowering drugs (statins or fibrates) in claims	Denominator Statement #6a: CKD beneficiaries and ESRD patients during the measurement period Numerator Statement #6a: CKD beneficiaries and ESRD patients in the denominator with a lipid profile test ordered during measurement period Denominator Statement #6b: CKD beneficiaries and ESRD patients in the denominator with PDE claims for a LLD during the measurement period Numerator Statement #6b: CKD beneficiaries and ESRD patients with ≥2 lipid profile tests ordered within 6 months or CKD beneficiaries and ESRD patients with LDL >130mg/dL and TG > 200mg/dL (if data is available from CMS-2728) during measurement period
Disease Specific Therapy #7 Percentage of CKD (Stages 3-5 pre-dialysis) beneficiaries and kidney transplant patients with claims for antihypertensive therapy	Denominator Statement #7a: CKD beneficiaries with a diagnosis of hypertension during the measurement period Numerator Statement #7a: CKD beneficiaries in the denominator with PDE claims for any antihypertensive therapy during measurement period Denominator Statement #7b: Kidney transplant patients with a diagnosis of hypertension during the measurement period Numerator Statement #7b: Kidney transplant patients in the denominator with PDE claims for any antihypertensive therapy during measurement period
Disease Specific Therapy #8 Percentage of CKD (Stages 3-5 pre-dialysis) beneficiaries and transplant patients with hypertension (HTN) on ACEI/ARB	Denominator Statement #8a: CKD beneficiaries with a diagnosis of hypertension during the measurement period Numerator Statement #8a: CKD beneficiaries in the denominator with PDE claims for any ACEI/ARB during measurement period Denominator Statement #8b: Kidney transplant patients with a diagnosis of hypertension during the measurement period Numerator Statement #8b: Kidney transplant patients in the denominator with PDE claims for any ACEI/ARB during measurement period

Table 3. Proposed Medication Measures for End Stage Renal Disease (ESRD) and Chronic Kidney Disease (CKD) (04/14/06)	
Measure Description	**Denominator and Numerator Statements**
Disease Specific Therapy #9 Percentage of CKD beneficiaries (Stages 3-5 pre-dialysis) and transplant patients with HTN on > once a day dosage regimen of antihypertensive drug	Denominator Statement #9a: CKD beneficiaries with a diagnosis of hypertension and PDE claims for antihypertensive therapy during the measurement period Numerator Statement #9a: CKD beneficiaries in the denominator with PDE claims for any antihypertensive drugs requiring >once a day dosing during measurement period Denominator Statement #9b: Kidney transplant patients with a diagnosis of hypertension and PDE claims for antihypertensive therapy during the measurement period Numerator Statement #9b: Kidney transplant patients in the denominator with PDE claims for any antihypertensive drugs requiring >once a day dosing during measurement period
Disease Specific Therapy #10 Percentage of CKD (Stages 4-5 pre-dialysis) beneficiaries, ESRD (dialysis) and transplant patients with claims for thiazide diuretics	Denominator Statement #10a: CKD beneficiaries and ESRD (dialysis) patients with no PDE claims for loop diuretics during the measurement period Numerator Statement #10a: CKD beneficiaries and ESRD (dialysis) patients in the denominator with PDE claims for thiazide diuretics during measurement period Denominator Statement #10b: Kidney transplant patients with no PDE claims for loop diuretics during the measurement period Numerator Statement #10b: Kidney transplant patients in the denominator with PDE claims for thiazide diuretics during measurement period
Disease Specific Therapy #11 Percentage of CKD 4 beneficiaries and kidney transplant patients with claims for potassium-sparing diuretics	Denominator Statement #11a: CKD beneficiaries with PDE claims for Part D drugs during the measurement period Numerator Statement #11a: CKD beneficiaries in the denominator with PDE claims for potassium sparing diuretics during measurement period Denominator Statement #11b: Kidney transplant patients with PDE claims for Part D drugs during the measurement period Numerator Statement #11b: Kidney transplant patients in the denominator with PDE claims for potassium sparing diuretics during measurement period
Therapeutic Monitoring Measures	
Therapeutic Monitoring #1 Therapeutic Monitoring for CKD (Stages 3-5 pre-dialysis) beneficiaries and ESRD patients on iron supplement	Denominator Statement: CKD beneficiaries/ ESRD patients with PDE (oral formulations) claims (intravenous) for iron supplement during the measurement period Numerator Statement: CKD beneficiaries/ESRD patients in the denominator with tests ordered for TSAT, serum ferritin, and Hgb (all 3) every 3 months of oral or intravenous iron therapy (initiation and persistent) during measurement period

Table 3. Proposed Medication Measures for End Stage Renal Disease (ESRD) and Chronic Kidney Disease (CKD) (04/14/06)	
Measure Description	**Denominator and Numerator Statements**
Therapeutic Monitoring #2 Therapeutic Monitoring for CKD (Stages 3-5 pre-dialysis) beneficiaries and ESRD patients with epoetin (EPO) and its analogue in claims	Denominator Statement #2a: CKD beneficiaries and ESRD patients with EPO (or its analogue) in PDE claims during the measurement period Numerator Statement #2a: CKD beneficiaries and ESRD patients in the denominator with anemia work up (tests ordered for TSAT, serum ferritin, and hemoglobin) 24 weeks prior to administration of EPO during measurement period Denominator Statement #2b: CKD beneficiaries and ESRD patients with EPO (or its analogue) in PDE claims during the measurement period Numerator Statement #2b: CKD beneficiaries and ESRD patients in the denominator with continuous therapeutic monitoring (tests ordered for TSAT, serum ferritin, and hemoglobin) within 24 weeks after administration of EPO therapy during measurement period
Therapeutic Monitoring #3 Therapeutic monitoring of active vitamin D sterol therapy among CKD (Stages 3-5 pre-dialysis) beneficiaries and ESRD patients	Denominator Statement #3a: CKD beneficiaries and ESRD patients with PDE or medical claims for active vitamin D sterol therapy during measurement period Numerator Statement #3a: CKD beneficiaries and ESRD patients in the denominator with tests for serum calcium, serum phosphorus, (1-84) PTH, and iPTH ordered within 6 months prior to initiation of vitamin D sterol therapy during measurement period Denominator Statement #3b: CKD beneficiaries and ESRD patients with PDE or medical claims for active vitamin D sterol therapy during measurement period Numerator Statement #3b: CKD beneficiaries and ESRD patients in the denominator with tests for serum calcium, serum phosphorus, (1-84) PTH, and iPTH ordered within 6 months after vitamin D sterol therapy during measurement period

2.3. STAKEHOLDERS WEBSITE

2.3.1. Purpose and Methods

Based on results from the TEP meeting, as well as follow-up conversations with TEP members, BearingPoint refined and amended the draft measures. After incorporating CMS input, the revised draft measures and an evaluation form were posted to a Stakeholders Website for comment by QIOs, ESRD Networks, large dialysis organizations, and other professional organizations.

The primary objectives of the Stakeholders Website were to:

- Distribute the MID to the stakeholders for evaluation and insight as to the practicality of its implementation

- Allow BearingPoint to further refine and amend the measures prior to convening the second TEP.

The Website went live on April 21, 2006 and remained open until May 22, 2006. The site featured an interactive design and interface to facilitate navigation and data collection.

2.3.1.1. Web Site Development

BearingPoint developed a comprehensive Website to communicate with stakeholders. It featured an interactive design and interface to facilitate navigation and data collection. The layout of the site featured several distinct web pages, and each page included a link to access the MID. A description of each web page is provided below, and samples of the web pages are included within Appendix G.

- Home Page: Defined the purpose of the website and provided a brief introduction. The page also directed users to the appropriate pages for further information on the project, objectives, and data collection method.
- Background: Included a more comprehensive description of ESRD Networks, the Medicare Modernization Act, and BearingPoint's contract with CMS. Further, it defined the scope of work for the contract and expectations for refinement of the measures based on the analysis of the stakeholders' comments.
- Purpose: Described the project contract, method of data analysis, structure and intent of the evaluation form, and role of the stakeholder when completing the form.
- Instructions: Provided detailed instructions on downloading the MID, definition of technical specifications, and an explanation of the evaluation form criteria. It also included assistance with the technical functions of the website and information on how to contact BearingPoint for technical assistance.
- Links: Provided website links to the official Medicare ESRD program site, ESRD Networks sites, and BearingPoint.
- Login/Create Account: Allowed stakeholders to register for access to the website and log in to access the evaluation form.

2.3.1.2. Identifying and Inviting Stakeholders

Per CMS guidance, BearingPoint's list of stakeholders for the CKD/ESRD measures included members of QIOs, ESRD Networks, large dialysis organizations, National Kidney Foundation, American Society of Pediatric Nephrology, American Society of Nephrology, Renal Physician Association, American Nephrology Nurses Association, and National Renal Administrators Association. However, organizations could also solicit feedback from other stakeholders whom they thought could provide valuable insight. Prior to the start of the comment period, BearingPoint and CMS sent reminder emails to all organizations and registered users restating the website close date and website URL.

2.3.1.3. Measure Input Document

The MID accepted by CMS on April 14, 2006 was posted on the Stakeholders Web site. The document described the Medication Measures Project and presented the proposed CKD/ESRD medication measures, which were based on the discussions held at the first TEP meeting. When at the website, stakeholders were requested to provide input and feedback regarding: the feasibility and relevancy of the potential measures, as well as the measures' usefulness for quality improvement purposes and for intervention in care delivery to Medicare beneficiaries with CKD and ESRD.

2.3.1.4. Managing the Website and Gathering Stakeholder Feedback

Stakeholders accessed the website through a link to a server stored on BearingPoint's network. Once on the Homepage, users were directed to the appropriate section of the website to find further information on the project, view evaluation instructions, and access the MID. To begin evaluating the measures, users were directed to the Login/Create Account page to register with BearingPoint. Users had to enter their first and last name, title, email address, password, organization name and type, and mailing address.

BearingPoint operated a help desk to answer inquires on technical difficulties for the duration of the comment period. All questions were directed to a dedicated BearingPoint email address and responded to within 24 hours. Metrics on help desk requests, as well as registration rates and the number of completed evaluations, were submitted to CMS on a weekly basis.

Information on each measure was collected using a Measure Evaluation Form designed by CMS and BearingPoint. Appendix G includes a sample Measure Evaluation Form. For each measure, stakeholders were asked to choose one of the following options:

- Accept without modification: Please include any overall comments on the measure.
- Accept with modification: Please include any suggestions on improving the measure along with a brief rationale for the modification.
- Delete measure: Please provide rationale for deleting the measure. Suggestions for new measures and specifications may also be included.

Stakeholders could also skip the measure without choosing one of the above options.

During the comment period, 23 individuals registered to review the MID and 11 commented on at least one measure. One respondent submitted comments by email in free form instead of completing the evaluation form, which brought total responses to 24 and 12, respectively. Two of the 12 responses accepted all measures without changes. Three responders were affiliated with ESRD Networks, three with QIOs, and the rest with professional organizations. Three responders were clinicians, one was a counselor (or patient advocate), two were quality improvement coordinators, and the rest were in managerial positions with their respective organizations. Of the 12 who did not comment on the measures, five were affiliated with ESRD

networks, four with QIOs, two with professional organizations, and one was a practicing nephrologist. One QIO submitted in-depth comments by email instead of completing the evaluation form online; one of the professional organizations submitted comments by email in addition to completing the evaluation form online. General comments regarding the measures and the MID, as well as specific measure feedback, were also collected through submissions emailed to the project team.

2.3.2. Summary of Stakeholder Comments

Stakeholder feedback mainly included measure-specific suggestions, but some stakeholders included general observations on the MID and its implementation. All comments on the MID and candidate measures were summarized and consolidated to reduce redundancy while maintaining the integrity of the input. While general themes emerged from the data, conflicting ideas on the best method for measurement remained and are reflected in the comments below. The revised MID, including Stakeholder comments, was submitted to CMS on July 3, 2006.

General topics and issues raised by stakeholders included the following:

- Inclusion of the pediatric population in the measures
- Lack of sensitivity and specificity in using drug proxies for identifying earlier stages of CKD (Stages 1-2) and underreporting of patients in earlier stages of CKD
- Deletion of the monitoring of erythropoiesis stimulating agents (ESA), as its usage is already closely scrutinized for reimbursement reasons
- Challenges of working with Part D drug claims data
- Reduction of the criterion for persistent therapy to 90 days from 180 days for some measures
- Lack of risk adjustment or exclusion criteria in the numerators and denominators
- Measures' readiness to be used for public reporting or accountability.

Revisions to the ESRD/CKD medication measures, based on the Stakeholder comments, are summarized for each domain in Table 4.

Table 4. Revisions to Measures based on Stakeholder Comments

Measure	Revisions
Patient Safety Measures	
Patient Safety #1 Percentage of chronic kidney disease (CKD) beneficiaries and end stage renal disease (ESRD) patients who had two or more drugs with the potential for a drug-drug interaction (DDI)	The measure was split into two measures: ✧ Percentage of ESRD patients who had two or more drugs with the potential for a DDI ✧ Percentage of CKD beneficiaries who had two or more drugs with the potential for a DDI

Table 4. Revisions to Measures based on Stakeholder Comments	
Measure	**Revisions**
Patient Safety #2 Percentage of CKD (Stages 3-5 pre-dialysis) beneficiaries with Drugs Requiring Caution (DRC)	The measure was accepted without modification
Patient Safety #3 Percentage of ESRD (dialysis) patients with Drugs Requiring Caution (DRC)	The measure was accepted without modification
Pharmacoeconomic Measures	
Pharmacoeconomics #1 Generic utilization ratio among drug claims for CKD (Stages 3-5 pre-dialysis) beneficiaries	The numerator and denominator were altered to include only medications that have a comparable generic therapeutic option Therefore, the measure was split into two measures with same numerator but different denominators, as follows: ✧ Denominator Statement #1a: Total number of Prescription Drug Event (PDE) claims for Part D covered drugs for CKD beneficiaries during the measurement period ✧ Denominator Statement #1b: Total number of PDE claims for Part D covered drugs with generic equivalent formulations for CKD beneficiaries during the measurement period
Pharmacoeconomics #2 Generic utilization ratio among drug claims for ESRD (dialysis) patients	The numerator and denominator were altered to include only medications that have a comparable generic therapeutic option Therefore, the measure was split into two measures with same numerator but different denominators, as follows: ✧ Denominator Statement #2a: Total number of PDE claims for Part D covered drugs for ESRD patients during the measurement period ✧ Denominator Statement #2b: Total number of PDE claims for Part D covered drugs for ESRD patients that have generic equivalent formulations during the measurement period
Disease-Specific Therapy Measures	
Disease- Specific Therapy #1 Percentage of claims for angiotensin converting enzyme inhibitors (ACEI)/ angiotensin receptor blockers (ARB) among CKD beneficiaries (Stages 3-5 pre-dialysis) with diabetes mellitus (DM)	The measure was accepted without modification
Disease- Specific Therapy #2 Percentage of claims for calcitriol, doxercalciferol, or paricalcitol among CKD beneficiaries (Stages 4-5 pre-dialysis) and ESRD (dialysis) patients	The measure's name remained the same. However, the denominators and numerators were modified to exclude the pediatric population. The pediatric population should be measured separately from the adult population

Table 4. Revisions to Measures based on Stakeholder Comments	
Measure	**Revisions**
Disease- Specific Therapy #3 Percentage of CKD beneficiaries (Stages 3-5 pre-dialysis) with claims for bisphosphonates who had been tested for serum PTH	The measurement period for PTH was changed to six months prior to claims instead of one year
Disease- Specific Therapy #4 ESRD (dialysis) patients with ≤ 1 Part D covered drug in claims	The measure names was changed to "ESRD (dialysis) patients with at least one Part D covered drug in claims"
Disease- Specific Therapy #5 CKD (Stages 3-5 pre-dialysis) beneficiaries with ≤ 1 Part D covered drug in claims	The measure names was changed to "CKD (Stages 3-5 pre-dialysis) beneficiaries with at least one Part D covered drug in claims"
Disease- Specific Therapy #6 Percentage of CKD beneficiaries and ESRD (dialysis) patients with lipid lowering drugs (statins or fibrates) in claims	The measure was split into four measures to report ESRD and CKD populations separately: ✧ Percentage of CKD beneficiaries with a lipid profile test ordered during the measurement period ✧ Percentage of CKD beneficiaries with ≥ 2 lipid profile tests ordered within 6 months or LDL >100mg/dL and TG > 200mg/dL during the measurement period ✧ Percentage of ESRD (dialysis) patients with a lipid profile test ordered during the measurement period ✧ Percentage of ESRD (dialysis) patients with ≥ 2 lipid profile tests ordered within 6 months or LDL >100mg/dL and TG > 200mg/dL during the measurement period
Disease- Specific Therapy #7 Percentage of CKD (Stages 3-5 pre-dialysis) beneficiaries and kidney transplant patients with claims for antihypertensive therapy	The measure was accepted without modification
Disease- Specific Therapy #8 Percentage of CKD (Stages 3-5 pre-dialysis) beneficiaries and transplant patients with hypertension (HTN) on ACEI/ARB	The measure was accepted without modification
Disease- Specific Therapy #9 Percentage of CKD beneficiaries (Stages 3-5 pre-dialysis) and transplant patients with hypertension (HTN) on > once a day dosage regimen of antihypertensive drug	The measure was accepted without modification
Disease- Specific Therapy #10 Percentage of CKD (Stages 4-5 pre-dialysis) beneficiaries, ESRD (dialysis), and transplant patients with claims for thiazide diuretics	The measure name was changed to "Percentage of CKD (Stages 4-5 pre-dialysis) beneficiaries and ESRD (dialysis) patients with claims for thiazide diuretics". The measure was split into two measures, reporting CKD and ESRD populations separately

Table 4. Revisions to Measures based on Stakeholder Comments	
Measure	**Revisions**
Disease- Specific Therapy #11 Percentage of CKD 4 beneficiaries and kidney transplant patients with claims for potassium-sparing diuretics	The measure was accepted without modification
Therapeutic Monitoring Measures	
Therapeutic Monitoring #1 Therapeutic Monitoring for CKD (Stages 3-5 pre-dialysis) beneficiaries and ESRD patients on iron supplement	The measure name was changed to "Percentage of ESRD patients on iron supplement who had therapeutic monitoring"
Therapeutic Monitoring #2 Therapeutic Monitoring of CKD (Stages 3-5 pre-dialysis) beneficiaries and ESRD patients with epoetin (EPO) and its analogue in claims	The measure name was changed to "Percentage of CKD (Stages 3-5 pre-dialysis) beneficiaries who had anemia evaluation prior to treatment with erythropoiesis stimulating agents (ESA)"
Therapeutic Monitoring #3 Therapeutic Monitoring of active vitamin D sterol therapy among CKD (Stages 3-5 pre-dialysis) beneficiaries and ESRD patients	The measure name was changed to "Percentage of CKD (Stages 3-5 pre-dialysis) beneficiaries and ESRD patients on vitamin D sterol therapy who had therapeutic monitoring". The measure was split into four measures, reporting CKD and ESRD populations separately. The four numerators statements are as follows: ✧ Numerator Statement #3a: CKD beneficiaries in the denominator with tests for serum calcium, serum phosphorus, (1-84) PTH, or iPTH ordered within 6 months prior to initiation of vitamin D sterol therapy during measurement period ✧ Numerator Statement #3b: CKD beneficiaries in the denominator with tests for serum calcium, serum phosphorus, (1-84) PTH, or iPTH ordered 6 months after initiation of vitamin D sterol therapy during measurement period ✧ Numerator Statement #3c: ESRD patients in the denominator with tests for serum calcium, serum phosphorus, (1-84) PTH, or iPTH ordered within 6 months prior to initiation of intravenous vitamin D sterol therapy during measurement period ✧ Numerator Statement #3d: ESRD patients in the denominator with tests for serum calcium, serum phosphorus, (1-84) PTH, or iPTH ordered within 6 months after initiation of intravenous vitamin D sterol therapy during measurement period

2.3.3. Revised Measures

Based on stakeholder feedback, BearingPoint refined and amended the CKD/ESRD medications measures. These revised measures were described within the MID submitted to CMS on July 3, 2006. The measures were classified into two measure sets:

- Measure Set 1 included measures that could be calculated using only Part D enrollment and drug claims data
- Measure Set 2 included measures that required additional data such as ICD-9-CM diagnosis codes, codes, and HCPCS) codes for drugs not covered by Part D in addition to the Part D enrollment and drug claims data.

Table 5 summarizes the revised ratios in Measure Set 1 and 19 ratios in Measure Set 2, as of July 3, 2006. The table includes each measure name, denominator statement, and numerator statement.

Table 5. Proposed Medication Measures for End Stage Renal Disease (ESRD) and Chronic Kidney Disease (CKD) (07/03/2006)

Measure Description	Numerator/Denominator
Measure Set 1. Measures Using Only Enrollment Data and Prescription Drug Event (PDE) Data	
Patient Safety Measures	
Patient Safety #1 Percentage of CKD beneficiaries and ESRD patients who had two or more drugs with the potential for a drug-drug interaction (DDI)	Denominator Statement #1a: ESRD patients with Prescription Drug Event (PDE) claims for any of the object and precipitant drugs during the measurement period Numerator Statement #1a: ESRD patients in the denominator with ≥1 potential drug-drug interactions (DDI) in PDE claims during measurement period Denominator Statement #1b: CKD beneficiaries with PDE for any of the object and precipitant drugs during the measurement period Numerator Statement #1b: CKD beneficiaries in the denominator with ≥1 potential DDI in PDE claims during measurement period
Patient Safety #2 Percentage of CKD (Stages 3-5 pre-dialysis) beneficiaries with Drugs Requiring Caution (DRC)	Denominator Statement: CKD beneficiaries with PDE claims for Part D covered drugs during the measurement period Numerator Statement: CKD beneficiaries in the denominator with ≥1 DRC in PDE claims during measurement period
Patient Safety #3 Percentage of ESRD (dialysis) patients with Drugs Requiring Caution (DRC)	Denominator Statement: ESRD patients with PDE claims for drugs during the measurement period Numerator Statement: ESRD patients in the denominator with ≥1 DRC in PDE claims during measurement period

Table 5. Proposed Medication Measures for End Stage Renal Disease (ESRD) and Chronic Kidney Disease (CKD) (07/03/2006)	
Measure Description	**Numerator/Denominator**
Pharmacoeconomic Measures	
Pharmacoeconomics #1 Percentage of generic utilization ratio among drug claims for CKD (Stages 3-5 pre-dialysis) beneficiaries	Denominator Statement #1a: Total number of PDE claims for Part D covered drugs for CKD beneficiaries during the measurement period Numerator Statement #1a: PDE claims for CKD beneficiaries in the denominator that are for generic formulations (identified by National Drug Codes (NDCs)) during measurement period Denominator Statement #1b: Total number of PDE claims for Part D covered drugs with generic equivalent formulations for CKD beneficiaries during the measurement period Numerator Statement #1b: PDE claims for CKD beneficiaries in the denominator that are for generic formulations (identified by NDCs) during the measurement period
Pharmacoeconomics #2 Percentage of generic utilization ratio among drug claims for ESRD (dialysis) patients	Denominator Statement #2a: Total number of PDE claims for Part D covered drugs for ESRD patients during the measurement period Numerator Statement #2a: PDE claims for ESRD patients in the denominator that are for generic formulations (identified by NDCs) during measurement period Denominator Statement #2b: Total number of PDE claims for Part D covered drugs for ESRD patients that have generic equivalent formulations during the measurement period Numerator Statement #2b: PDE claims for ESRD patients in the denominator that are for generic formulations (identified by NDCs) during measurement period
Disease Specific Therapy Measures	
Disease Specific Therapy #1 Percentage of claims for angiotensin converting enzyme inhibitors (ACEI)/ angiotensin receptor blockers (ARB) among CKD beneficiaries (Stages 3-5 pre-dialysis) with diabetes mellitus (DM)	Denominator Statement: Diabetic CKD beneficiaries with PDE claims for Part D covered drugs during the measurement period Numerator Statement: CKD beneficiaries in the denominator with PDE claims for ACEI/ARB during measurement period
Disease Specific Therapy #4 ESRD (dialysis) patients with at least one Part D covered drug in claims	Denominator Statement: ESRD patients eligible for Part D benefits during the measurement period Numerator Statement: ESRD patients in the denominator with at least 1 Part D covered drug in PDE claims during measurement period
Disease Specific Therapy #5 CKD (Stages 3 to 5 pre-dialysis) beneficiaries with at least one Part D covered drug in claims	Denominator Statement: CKD beneficiaries eligible for Part D benefits during the measurement period Numerator Statement: CKD beneficiaries in the denominator with at least 1 Part D covered drug in PDE claims during measurement period

Table 5. Proposed Medication Measures for End Stage Renal Disease (ESRD) and Chronic Kidney Disease (CKD) (07/03/2006)	
Measure Description	**Numerator/Denominator**
Disease Specific Therapy #10 Percentage of CKD (Stages 4-5 pre-dialysis) beneficiaries and ESRD (dialysis) patients with claims for thiazide diuretics	Denominator Statement #10a: CKD beneficiaries with no PDE claims for loop diuretics during the measurement period Numerator Statement #10a: CKD beneficiaries in the denominator with PDE claims for thiazide diuretics during measurement period Denominator Statement #10b: ESRD patients with no PDE claims for loop diuretics during the measurement period Numerator Statement #10b: ESRD patients in the denominator with PDE claims for thiazide diuretics during measurement period
Disease Specific Therapy #11 Percentage of CKD 4 beneficiaries and kidney transplant patients with claims for potassium-sparing diuretics	Denominator Statement #11a: CKD beneficiaries with PDE claims for Part D drugs during the measurement period Numerator Statement #11a: CKD beneficiaries in the denominator with PDE claims for potassium sparing diuretics during measurement period Denominator Statement #11b: Kidney transplant patients with PDE claims for Part D drugs during the measurement period Numerator Statement #11b: Kidney transplant patients in the denominator with PDE claims for potassium sparing diuretics during measurement period
Measure Set 2. Quality Measures Requiring Additional Data	
Disease Specific Therapy Measures	
Disease Specific Therapy #2 Percentage of claims for calcitriol, doxercalciferol, or paricalcitol among CKD beneficiaries (Stages 4-5 pre- dialysis) and ESRD (dialysis) patients	Denominator Statement #2a: CKD (Stages 4-5 pre-dialysis) beneficiaries with ≥1 PDE claims for Part D drugs during the measurement period Numerator Statement #2a: CKD beneficiaries in the denominator with PDE claims for an oral formulation of active vitamin D sterol during measurement period Denominator Statement #2b: ESRD patients with medical claims during the measurement period Numerator Statement #2b: ESRD patients in the denominator with medical claims for intravenous vitamin D sterol therapy during the measurement period
Disease Specific Therapy #3 Percentage of CKD beneficiaries (Stages 3-5 pre-dialysis) with claims for bisphosphonates who had been tested for serum parathyroid hormone (PTH)	Denominator Statement: CKD beneficiaries (Stages 3-5 pre-dialysis) with PDE claims for bisphosphonates during the measurement period Numerator Statement: CKD beneficiaries in the denominator who had at least one claim for serum PTH within 6 months prior to PDE claims for bisphosphonate during the measurement period

Table 5. Proposed Medication Measures for End Stage Renal Disease (ESRD) and Chronic Kidney Disease (CKD) (07/03/2006)

Measure Description	Numerator/Denominator
Disease Specific Therapy #6 Percentage of CKD beneficiaries and ESRD (dialysis) patients with lipid lowering drugs (LLDs) (statins or fibrates) in claims	Denominator Statement #6a: CKD beneficiaries during the measurement period Numerator Statement #6a: CKD beneficiaries in the denominator with a lipid profile test ordered during measurement period Denominator Statement #6b: CKD beneficiaries in the denominator with PDE claims for a LLD during the measurement period Numerator Statement #6b: CKD beneficiaries with ≥2 lipid profile tests ordered within 6 months or CKD beneficiaries with LDL >100mg/dL and TG > 200mg/dL during measurement period Denominator Statement #6c: ESRD patients during the measurement period Numerator Statement #6c: ESRD patients in the denominator with a lipid profile test ordered during measurement period Denominator Statement #6d: ESRD patients in the denominator with PDE claims for a LLD during the measurement period Numerator Statement #6d: ESRD beneficiaries with ≥2 lipid profile tests ordered within 6 months or ESRD beneficiaries with LDL >100mg/dL and TG > 200mg/dL (if data is available from CMS-2728) during measurement period
Disease Specific Therapy #7 Percentage of CKD (Stages 3-5 pre-dialysis) beneficiaries and kidney transplant patients with claims for antihypertensive therapy	Denominator Statement #7a: CKD beneficiaries with a diagnosis of hypertension during the measurement period Numerator Statement #7a: CKD beneficiaries in the denominator with PDE claims for any antihypertensive therapy during measurement period Denominator Statement #7b: Kidney transplant patients with a diagnosis of hypertension during the measurement period Numerator Statement #7b: Kidney transplant patients in the denominator with PDE claims for any antihypertensive therapy during measurement period
Disease Specific Therapy #8 Percentage of CKD (Stages 3-5 pre-dialysis) beneficiaries and transplant patients with hypertension (HTN) on ACEI/ARB	Denominator Statement #8a: CKD beneficiaries with a diagnosis of hypertension during the measurement period Numerator Statement #8a: CKD beneficiaries in the denominator with PDE claims for any ACEI/ARB during measurement period Denominator Statement #8b: Kidney transplant patients with a diagnosis of hypertension during the measurement period Numerator Statement #8b: Kidney transplant patients in the denominator with PDE claims for any ACEI/ARB during measurement period

Table 5. Proposed Medication Measures for End Stage Renal Disease (ESRD) and Chronic Kidney Disease (CKD) (07/03/2006)	
Measure Description	**Numerator/Denominator**
Disease Specific Therapy #9 Percentage of CKD beneficiaries (Stages 3-5 pre-dialysis) and transplant patients with HTN on > once a day dosage regimen of antihypertensive drug	Denominator Statement #9a: CKD beneficiaries with a diagnosis of hypertension or PDE claims for antihypertensive therapy during the measurement period Numerator Statement #9a: CKD beneficiaries in the denominator with PDE claims for any antihypertensive drugs requiring > once a day dosing during measurement period Denominator Statement #9b: Kidney transplant patients with a diagnosis of hypertension and PDE claims for antihypertensive therapy during the measurement period Numerator Statement #9b: Kidney transplant patients in the denominator with PDE claims for any antihypertensive drugs requiring > once a day dosing during measurement period
Therapeutic Monitoring Measures	
Therapeutic Monitoring #1 Percentage of ESRD patients on iron supplement who had therapeutic monitoring	Denominator Statement: ESRD patients in the denominator with medical claims for intravenous iron supplement during the measurement period Numerator Statement: ESRD patients in the denominator with tests ordered for Transferrin Saturation (TSAT), serum ferritin, and Hgb (all 3) at intervals ≤3 months during measurement period
Therapeutic Monitoring #2 Percentage of CKD (Stages 3-5 pre-dialysis) beneficiaries who had anemia evaluation prior to treatment with erythropoiesis stimulating agents (ESA)	Denominator Statement: CKD beneficiaries with PDE for ESA during the measurement period Numerator Statement: CKD (Stages 3-5 pre-dialysis) beneficiaries in the denominator who had anemia evaluation (tests ordered for TSAT, serum ferritin, and Complete Blood Count) prior to administration of ESA during measurement period

Table 5. Proposed Medication Measures for End Stage Renal Disease (ESRD) and Chronic Kidney Disease (CKD) (07/03/2006)	
Measure Description	**Numerator/Denominator**
Therapeutic Monitoring #3 Percentage of CKD (Stages 3-5 pre-dialysis) beneficiaries and ESRD patients on vitamin D sterol therapy who had therapeutic monitoring	Denominator Statement #3a: CKD beneficiaries with PDE claims for oral vitamin D sterol therapy during the measurement period Numerator Statement #3a: CKD beneficiaries in the denominator with tests for serum calcium, serum phosphorus, (1-84) PTH, or iPTH ordered within 6 months prior to initiation of vitamin D sterol therapy during measurement period Denominator Statement #3b: CKD beneficiaries with PDE claims for oral vitamin D sterol therapy during the measurement period Numerator Statement #3b: CKD beneficiaries in the denominator with tests for serum calcium, serum phosphorus, (1-84) PTH, or iPTH ordered 6 months after initiation of vitamin D sterol therapy during measurement period Denominators Statement: #3c: ESRD patients with medical claims for intravenous vitamin D sterol therapy during the measurement period Numerator Statement #3c: ESRD patients in the denominator with tests for serum calcium, serum phosphorus, (1-84) PTH, or iPTH ordered within 6 months prior to initiation of intravenous vitamin D sterol therapy during measurement period Denominators Statement: #3d: ESRD patients with medical claims for intravenous vitamin D sterol therapy during the measurement period Numerator Statement #3d: ESRD patients in the denominator with tests for serum calcium, serum phosphorus, (1-84) PTH, or iPTH ordered within 6 months after initiation of intravenous vitamin D sterol therapy during measurement period

2.3.4. Revised MID

In preparation for the Second TEP Meeting, CMS and the BearingPoint team further refined the CKD/ESRD medication measures. The revised MID reflected additional updates that made the naming and numbering of the measures consistent.

Table 6 summarizes the ESRD/CKD revised medication measures as of September 28, 2006. The table includes the measure name, denominator statement, and numerator statement.

Table 6. Proposed Medication Measures for End Stage Renal Disease (ESRD) and Chronic Kidney Disease (CKD) (09/28/2006)	
Measure Description	**Numerator/Denominator**
Measure Set 1. Measures Using Only Enrollment Data and Prescription Drug Event (PDE) Data	
Patient Safety Measures	
Patient Safety #1 Percentage of CKD (Stages 3-5 pre-dialysis) beneficiaries and ESRD patients who have two or more drugs with the potential to interact (DDI)	Denominator Statement #1a: ESRD patients with Prescription Drug Event (PDE) claims for any of the object and precipitant drugs during the measurement period Numerator Statement #1a: ESRD patients in the denominator with ≥1 potential Drug-Drug Interaction (DDI) in PDE claims during measurement period Denominator Statement #1b: CKD beneficiaries with PDE for any of the object and precipitant drugs during the measurement period Numerator Statement #1b: CKD beneficiaries in the denominator with ≥1 potential DDI in PDE claims during measurement period
Patient Safety #2 Percentage of CKD (Stages 3-5 pre-dialysis) beneficiaries with Drugs Requiring Caution (DRC)	Denominator Statement: CKD beneficiaries with PDE claims for Part D covered drugs during the measurement period Numerator Statement: CKD beneficiaries in the denominator with ≥1 DRC in PDE claims during measurement period
Patient Safety #3 Percentage of ESRD (dialysis) patients with Drugs Requiring Caution (DRC)	Denominator Statement: ESRD patients with PDE claims for drugs during the measurement period Numerator Statement: ESRD patients in the denominator with ≥1 DRC in PDE claims during measurement period
Pharmacoeconomic Measures	
Pharmacoeconomics #1 Percentage of generic utilization ratio among drug claims for CKD (Stages 3-5 pre-dialysis) beneficiaries	Denominator Statement #1a: Total number of PDE claims (absolute) for Part D covered drugs for CKD beneficiaries during the measurement period Numerator Statement #1a: PDE claims for CKD beneficiaries in the denominator that are for generic formulations (identified by National Drug Codes (NDCs)) during measurement period Denominator Statement #1b: Total number of PDE claims for Part D covered drugs with generic equivalent formulations (adjusted) for CKD beneficiaries during the measurement period Numerator Statement #1b: PDE claims for CKD beneficiaries in the denominator that are for generic formulations (identified by NDCs) during the measurement period

Table 6. Proposed Medication Measures for End Stage Renal Disease (ESRD) and Chronic Kidney Disease (CKD) (09/28/2006)	
Measure Description	**Numerator/Denominator**
Pharmacoeconomics #2 Percentage of generic utilization ratio among drug claims for ESRD (dialysis) patients	Denominator Statement #2a: Total number of PDE claims (absolute) for Part D covered drugs for ESRD patients during the measurement period Numerator Statement #2a: PDE claims for ESRD patients in the denominator that are for generic formulations (identified by NDCs) during measurement period Denominator Statement #2b: Total number of PDE claims for Part D covered drugs for ESRD patients that have generic equivalent formulations (adjusted) during the measurement period Numerator Statement #2b: PDE claims for ESRD patients in the denominator that are for generic formulations (identified by NDCs) during measurement period
Disease Specific Therapy Measures	
Disease Specific Therapy #1 Percentage of CKD beneficiaries (Stages 3-5 pre-dialysis) with diabetes mellitus (DM) who have claims for angiotensin converting enzyme inhibitors (ACEI)/ angiotensin receptor blockers (ARB)	Denominator Statement: Diabetic CKD beneficiaries with PDE claims for Part D covered drugs during the measurement period Numerator Statement: CKD beneficiaries in the denominator with PDE claims for ACEI/ARB during measurement period
Disease Specific Therapy #4 Percentage of ESRD (dialysis) patients with at least one Part D covered drug in claims	Denominator Statement: ESRD patients eligible for Part D benefits during the measurement period Numerator Statement: ESRD patients in the denominator with at least 1 Part D covered drug in PDE claims during measurement period
Disease Specific Therapy #5 Percentage of CKD (Stages 3-5 pre-dialysis) beneficiaries with at least one Part D covered drug in claims	Denominator Statement: CKD beneficiaries eligible for Part D benefits during the measurement period Numerator Statement: CKD beneficiaries in the denominator with at least 1 Part D covered drug in PDE claims during measurement period
Disease Specific Therapy #10 Percentage of CKD (Stages 4-5 pre-dialysis) beneficiaries and ESRD (dialysis) patients with claims for thiazide but no loop diuretics	Denominator Statement #10a: CKD beneficiaries with at least one PDE claim during the measurement period Numerator Statement #10a: CKD beneficiaries in the denominator with PDE claims for thiazide diuretics, but no loop diuretics during measurement period Denominator Statement #10b: ESRD patients with at least one PDE claim during the measurement period Numerator Statement #10b: ESRD patients in the denominator with PDE claims for thiazide diuretics, but no loop diuretics during measurement period

Table 6. Proposed Medication Measures for End Stage Renal Disease (ESRD) and Chronic Kidney Disease (CKD) (09/28/2006)	
Measure Description	**Numerator/Denominator**
Disease Specific Therapy #11 Percentage of CKD (Stages 3-5 pre-dialysis) beneficiaries and ESRD (transplant) patients with claims for potassium-sparing diuretics	Denominator Statement #11a: CKD beneficiaries with PDE claims for Part D drugs during the measurement period Numerator Statement #11a: CKD beneficiaries in the denominator with PDE claims for potassium sparing diuretics during measurement period Denominator Statement #11b: Kidney transplant patients with PDE claims for Part D drugs during the measurement period Numerator Statement #11b: Kidney transplant patients in the denominator with PDE claims for potassium sparing diuretics during measurement period
Measure Set 2. Quality Measures Requiring Additional Data	
Disease Specific Therapy Measures	
Disease Specific Therapy #2 Percentage of CKD (Stages 4-5 pre-dialysis) beneficiaries and ESRD (dialysis) patients who have claims for calcitriol, doxercalciferol, or paricalcitol	Denominator Statement #2a: CKD (Stages 4-5 pre-dialysis) beneficiaries with ≥ 1 PDE claims for Part D drugs during the measurement period Numerator Statement #2a: CKD beneficiaries in the denominator with PDE claims for an oral formulation of active vitamin D sterol during measurement period Denominator Statement #2b: ESRD patients with medical claims during the measurement period Numerator Statement #2b: ESRD patients in the denominator with medical claims for intravenous vitamin D sterol therapy during measurement period
Disease Specific Therapy #3 Percentage of CKD beneficiaries (Stages 3-5 pre-dialysis) with claims for bisphosphonates who had been tested for serum parathyroid hormone (PTH)	Denominator Statement: CKD beneficiaries (Stages 3-5 pre-dialysis) with PDE claims for bisphosphonte during the measurement period Numerator Statement: CKD beneficiaries in the denominator who had at least one claim for serum PTH within 6 months prior to PDE claims for bisphosphonate during measurement period

Table 6. Proposed Medication Measures for End Stage Renal Disease (ESRD) and Chronic Kidney Disease (CKD) (09/28/2006)	
Measure Description	**Numerator/Denominator**
Disease Specific Therapy #6 Percentage of CKD beneficiaries (Stages 3-5 pre-dialysis) and ESRD (dialysis) patients with abnormal lipid profiles who have claims for lipid lowering drugs (LLDs) (statins or fibrates)	Denominator Statement #6a: CKD beneficiaries during the measurement period Numerator Statement #6a: CKD beneficiaries in the denominator with a lipid profile test ordered during measurement period Denominator Statement #6b: CKD beneficiaries in the denominator with PDE claims for a LLD during the measurement period Numerator Statement #6b: CKD beneficiaries with ≥2 lipid profile tests ordered within 6 months or CKD beneficiaries with LDL >100mg/dL and TG > 200mg/dL during measurement period Denominator Statement #6c: ESRD patients during the measurement period Numerator Statement #6c: ESRD patients in the denominator with a lipid profile test ordered during measurement period Denominator Statement #6d: ESRD patients in the denominator with PDE claims for a LLD during the measurement period Numerator Statement #6d: ESRD beneficiaries with ≥2 lipid profile tests ordered within 6 months or ESRD beneficiaries with LDL >100mg/dL and TG > 200mg/dL (if data is available from CMS-2728) during measurement period
Disease Specific Therapy #7 Percentage of CKD (Stages 3-5 pre-dialysis) beneficiaries and ESRD (transplant) patients with elevated blood pressure who have claims for antihypertensive therapy	Denominator Statement #7a: CKD beneficiaries with a diagnosis of hypertension during the measurement period Numerator Statement #7a: CKD beneficiaries in the denominator with PDE claims for any antihypertensive therapy during measurement period Denominator Statement #7b: Kidney transplant patients with a diagnosis of hypertension during the measurement period Numerator Statement #7b: Kidney transplant patients in the denominator with PDE claims for any antihypertensive therapy during measurement period
Disease Specific Therapy #8 Percentage of CKD (Stages 3-5 pre-dialysis) beneficiaries and ESRD (transplant) patients with elevated blood pressure who have claims for ACEI/ARB	Denominator Statement #8a: CKD beneficiaries with a diagnosis of hypertension during the measurement period Numerator Statement #8a: CKD beneficiaries in the denominator with PDE claims for any ACEI/ARB during measurement period Denominator Statement #8b: Kidney transplant patients with a diagnosis of hypertension during the measurement period Numerator Statement #8b: Kidney transplant patients in the denominator with PDE claims for any ACEI/ARB during measurement period

Table 6. Proposed Medication Measures for End Stage Renal Disease (ESRD) and Chronic Kidney Disease (CKD) (09/28/2006)	
Measure Description	**Numerator/Denominator**
Disease Specific Therapy #9 Percentage of CKD beneficiaries (Stages 3-5 pre-dialysis) and ESRD (transplant) patients with elevated blood pressure who have a more than once-a-day dosage regimen of antihypertensive drug	Denominator Statement #9a: CKD beneficiaries with a diagnosis of hypertension and PDE claims for antihypertensive therapy during the measurement period Numerator Statement #9a: CKD beneficiaries in the denominator with PDE claims for any antihypertensive drugs requiring > once-a-day dosing during measurement period Denominator Statement #9b: Kidney transplant patients with a diagnosis of hypertension and PDE claims for antihypertensive therapy during the measurement period Numerator Statement #9b: Kidney transplant patients in the denominator with PDE claims for any antihypertensive drugs requiring > once-a-day dosing during measurement period
Therapeutic Monitoring Measures	
Therapeutic Monitoring #1 Percentage of ESRD patients on iron supplement who had therapeutic monitoring	Denominator Statement: ESRD patients with medical claims for intravenous iron supplement during the measurement period Numerator Statement: ESRD patients in the denominator with tests ordered for Transferrin Saturation (TSAT), serum ferritin, and Hgb (all 3) at intervals ≤3 months during measurement period
Therapeutic Monitoring #2 Percentage of CKD (Sages 3-5 pre-dialysis) beneficiaries who had anemia evaluation prior to treatment with erythropoiesis stimulating agents (ESA)	Denominator Statement: CKD beneficiaries with PDE for ESA during the measurement period Numerator Statement: CKD (Stages 3-5 pre-dialysis) beneficiaries in the denominator who had anemia evaluation (tests ordered for TSAT, serum ferritin, and Complete Blood Count) prior to administration of ESA during measurement period

Table 6. Proposed Medication Measures for End Stage Renal Disease (ESRD) and Chronic Kidney Disease (CKD) (09/28/2006)	
Measure Description	**Numerator/Denominator**
Therapeutic Monitoring #3 Percentage of CKD (Stages 3-5 pre-dialysis) beneficiaries and ESRD (dialysis) patients on vitamin D sterol therapy who had therapeutic monitoring	Denominator Statement #3a: CKD beneficiaries with PDE claims for oral vitamin D sterol therapy during the measurement period Numerator Statement #3a: CKD beneficiaries in the denominator with tests for serum calcium, serum phosphorus, (1-84) PTH, or iPTH ordered within 6 months prior to initiation of vitamin D sterol therapy during measurement period Denominator Statement #3b: CKD beneficiaries with PDE claims for oral vitamin D sterol therapy during the measurement period Numerator Statement #3b: CKD beneficiaries in the denominator with tests for serum calcium, serum phosphorus, (1-84) PTH, or iPTH ordered 6 months after initiation of vitamin D sterol therapy during measurement period Denominators Statement: #3c: ESRD patients with medical claims for intravenous vitamin D sterol therapy during the measurement period Numerator Statement #3c: ESRD patients in the denominator with tests for serum calcium, serum phosphorus, (1-84) PTH, or iPTH ordered within 6 months prior to initiation of intravenous vitamin D sterol therapy during measurement period Denominators Statement #3d: ESRD patients with medical claims for intravenous vitamin D sterol therapy during the measurement period Numerator Statement #3d: ESRD patients in the denominator with tests for serum calcium, serum phosphorus, (1-84) PTH, or iPTH ordered within 6 months after initiation of intravenous vitamin D sterol therapy during measurement period

2.4. STAKEHOLDERS MEETING

2.4.1. Purpose and Methods

To inform stakeholders about the progress of the CKD/ESRD candidate measures and to obtain additional input and feedback from the renal community, BearingPoint organized the CKD/ESRD Stakeholders Meeting in Baltimore, MD, on October 10, 2006.

The primary purposes of the meeting were to:

- Discuss the proposed set of medication measures under development
- Obtain additional feedback to be discussed during the second TEP Meeting on the following day.

To provide background and context for attendees, CMS distributed the revised draft MID (submitted to CMS on September 28, 2006) prior to the meeting and prepared a presentation describing the project's accomplishments to date. In addition to soliciting input about the medication measures being developed under this contract, the meeting afforded CMS an opportunity to update stakeholders on several other ESRD-related initiatives.

2.4.2. Meeting Agenda

To provide background and context for the medication measures, CMS presented the current status of the CKD/ESRD population and the challenges facing the renal community, while BearingPoint presented an overview of the CKD/ESRD Medication Measure Project. The one-day agenda also included presentations on the initiatives of the Kidney Care Quality Alliance (KCQA), National Quality Forum (NQF), Physician Advisory Committee, and the Clinical Performance Measures (CPMs) Project. Appendix H shows the Stakeholders Meeting Agenda.

2.4.3. Summary of Stakeholder Feedback

During the Stakeholders Meeting, TEP members in attendance answered questions related to the measures. A detailed description of the stakeholders' comments was included in the Stakeholders Meeting Summary Report, submitted to CMS on November 16, 2006.

The main points of discussion raised during the Stakeholders Meeting included the following:

- Future use of the CKD/ESRD Medication Measures for public reporting and pay-for-performance initiatives
- Existence of numerous measures development initiatives without a coordination mechanism in place to align them
- Safety issues involved in the use of lipid-lowering drugs (LLDs) in patients with high lipid profiles
- Existence of literature and evidence-based research regarding the use of potassium-sparing diuretics in CKD patients

- Description of the process of selecting, maintaining, and updating the list of Drugs Requiring Caution (DRC), and availability of CMS funding for updating this list
- Viability and usefulness of the CKD/ESRD Medication Measures, given the inability to access inpatient hospital, outpatient hospital, and physician claims data, and laboratory results.

2.5. SECOND TECHNICAL EXPERT PANEL MEETING

2.5.1. Purpose and Methods

Following the Stakeholders Meeting, CMS and BearingPoint convened a second TEP meeting on October 11, 2006. The purpose of this TEP session was to discuss the comments received during the Stakeholders Meeting and to review and further refine the proposed measures.

BearingPoint invited the TEP members who participated in the January meeting. Each member was assigned to the same workgroup as the first TEP meeting.[4] A TEP member facilitated each workgroup and was supported by two BearingPoint project staff – a key technical staff person and a note taker. The team recommended that each group include a subject matter expert (e.g., a physician or pharmacist), a data claims expert, a quality improvement expert (e.g., someone who has worked directly or as a consultant for QIOs), an ESRD Network or LDO expert, a government official or individual with quality measurement development experience, and a patient advocate. Appendix I shows the workgroups and measure assignments.

2.5.2. Meeting Agenda and Organization

Prior to arrival at the TEP meeting, BearingPoint emailed each TEP member the revised MID (dated September 28, 2006) and an evaluation form for each measure assigned to that panelist's workgroup. BearingPoint conducted telephone conferences with the TEP members and workgroup facilitators to discuss the purpose of the TEP, each member's role and responsibilities, the expectations for the meeting, and the aforementioned materials.

The evaluation forms asked panelists to accept, accept with modification, or delete each of the measures. They also solicited TEP members' opinions on the measure's numerator and denominator statements and references or literature related to the measures. The forms also included measure-specific questions or issues for which the team was seeking TEP guidance. Appendix J includes a sample Evaluation Form.

The one-day meeting began with opening remarks by CMS and BearingPoint, and a presentation by Dr. Paul Scheel on the comments and questions raised during the previous day's Stakeholders Meeting. Appendix K includes a copy of the agenda. The TEP members then separated into workgroups to review and discuss their assigned measures. During the workgroup sessions, TEP members were asked to evaluate five to six measures and develop a

[4] Because most of the original TEP members from workgroup 2 were unable to attend the second TEP meeting, Dr. Curtis Johnson was reassigned to workgroup 2.

consensus on whether to accept the measure as written, accept with modification, or delete. The meeting concluded with a roundtable discussion, during which each workgroup facilitator summarized the recommendations for each measure.

2.5.3. Summary of TEP Review

The TEP provided general comments on the overall set of measures as well as each draft candidate measure. Highlights from the TEP review are listed below. A more detailed description of the TEP's comments was included in the TEP Summary Report, submitted to CMS on November 27, 2006. General comments about the measures included:

Workgroup 1 – Patient Safety and Drug Utilization

Overall, Workgroup 1 suggested to:

- Clarify and limit the definition of ESRD population to dialysis population
- Not exclude from the eligible population deceased beneficiaries, even if the enrollment criterion related to the number of months eligibility is not met (exclusion may bias the statistic)
- Report statistics separately for the CKD (defined by drug proxy and including functioning transplants) and the ESRD (dialysis) populations. As a consequence, the drug-drug interaction measure was split into four measures with each population having two separate denominators.

Workgroup 1 agreed to modify the names of the following measures:

- Percentage of ESRD (dialysis) patients with drugs requiring caution to percentage of ESRD (dialysis) patients with drugs to be avoided
- Percentage of CKD (stages 3, 4, and 5 pre-dialysis) beneficiaries with drugs requiring caution to percentage of CKD (stages 3, 4, and 5 pre-dialysis) beneficiaries with drugs requiring appropriate dosing.

Workgroup 2 – Cardiovascular Disease (CVD) in ESRD and CKD

Workgroup 2 agreed to delete the following measures:

- Percentage of ESRD (dialysis) patients with claims for thiazide diuretics, but no loop diuretics
- Percentage of CKD beneficiaries with elevated blood pressure who have claims for ACEI/ ARB
- Percentage of ESRD transplant beneficiaries with elevated blood pressure who have claims for ACEI/ARB.

Workgroup 2 advised moving the following measures to Measures Set 2:

- Percentage of CKD (Stages 3, 4, and 5 pre-dialysis) beneficiaries and ESRD (dialysis) patients with abnormal lipid profiles who have claims for lipid lowering drugs (statins or fibrates)
- Percentage of ESRD (dialysis) patients with claims for thiazide diuretics, but no loop diuretics.

Workgroup 3 – Therapeutic Monitoring

Workgroup 3 agreed to delete the following measure:

- Percentage of ESRD patients on iron supplement who have therapeutic monitoring.

Workgroup 3 advised moving the following measure to Measure Set 2:

- Percentage of CKD (Stages 3, 4, and 5 pre-dialysis) beneficiaries who had anemia evaluation prior to treatment with ESA.

Tables 7a to 7e summarize the TEP's comments and recommendations by domain and measure.

Table 7a. Revisions to Measures based on Technical Expert Panel (TEP) Comments

Measure Set 1. Quality Measures Using Only Enrollment and Prescription Drug Event (PDE) Data
Domain 1: Patient Safety
1.1a Percentage of ESRD patients who have 2 or more drugs with the potential to interact
1.1b Percentage of CKD beneficiaries who have 2 or more drugs with the potential to interact
1. Document the reference source and methodology for selection of the drug pairs with potential to interact. If Facts & Comparisons is used, explain what constitutes level "1" interaction. 2. With respect to temporality, include potential drug pairs "administered" within 14 days between the end date of the object drug and start day of the precipitant drug. 3. Drug-Drug Interaction (DDI) list should be updated regularly. CMS should decide on a custodian for the drug list and update it periodically (interval to be determined). 4. Statistics should be reported separately for the CKD (defined by drug proxy) and the ESRD (dialysis) population. Transplant patients would be identified by drug proxy and included with the CKD population. Immunosuppressant drugs will not be included in the DDI calculation (outside of scope). 5. For eligible population, drug claims for deceased beneficiaries should not be excluded, even if the enrollment criterion is not met (exclusion may bias the statistic). 6. Standard Information management System (SIMS) provides a very complete and current data source for the ESRD population (dialysis and transplant included). The ESRD denominator should be considered the universe of Medicare-eligible ESRD patients. 7. Two separate denominators for CKD and ESRD measures: 1) all CKD, 2) CKD who had at least one drug on DDI list (precipitant or object). Same for ESRD.

Table 7a. Revisions to Measures based on Technical Expert Panel (TEP) Comments (cont'd)

Measure Set 1. Quality Measures Using Only Enrollment and Prescription Drug Event (PDE) Data
Domain 1: Patient Safety
1.2 Percentage of CKD beneficiaries with drugs requiring caution (DRC)
1. Renumber so that (a) is associated with ESRD, (b) is associated with CKD. 2. Measure should be re-phrased as "drugs requiring appropriate dosing" because some are unavoidable. 3. Methodology for selection of the list should be documented. (Since this list could be very long, some research assistance, internal or external, may be needed to revise the list.) 4. An incidence statistic at the population level as currently proposed may not be useful for quality improvement or intervention. To make this measure actionable, a drill-down analysis at the individual drug level should be performed to identify the drugs with most common occurrences. (This drill down analysis is outside the scope of this contract because each computation would constitute one measure, thus resulting in "hundreds of measures." Although programming for the frequency identification is not very difficult, writing the technical specifications for this may be challenging. This level of analysis can be suggested for the future but may not be necessary for the current contract.) 5. Angiotensin converting enzyme inhibitors (ACEI) and angiotensin receptor blockers (ARB) should be added to this list for appropriate dosing.
1.3 Percentage of ESRD patients with drugs requiring caution (DRC)
1. Renumber this measure to be 1.2a to be consistent with above. 2. This measure can be re-phrased as "drugs to be avoided" because the origin of this list is grounded in the recommended list from the ESRD Network 8 report. This is a good starting point but should also be updated regularly, as should the DDI list. 3. The list of 29 drugs (as reported by the ESRD Network 8 project) should be separated from the CKD list. 4. Morphine (short- and long-acting) and meperidine should be included in this list (recommendation from Group 2).

Table 7b. Revisions to Measures based on Technical Expert Panel (TEP) Comments

Measure Set 1. Quality Measures Using Only Enrollment and Prescription Drug Event (PDE) Data
Domain 2: Pharmacoeconomics
2.1a Percentage of generic utilization (absolute) among drug claims for CKD beneficiaries
2.1b Percentage of generic utilization (adjusted) among drug claims for CKD beneficiaries
2.2a Percentage of generic utilization (absolute) among drug claims for ESRD patients
2.2b Percentage of generic utilization (adjusted) among drug claims for ESRD patients
1. The generic utilization ratios as proposed are accepted as currently defined. 2. Calculating the ratios separately for the two populations, CKD and ESRD (dialysis and transplant), is meaningful because there are drugs widely used by the CKD population that are single source (e.g. ARB). The same is also true for drugs taken by the ESRD patients. 3. Renumber to be consistent: 2.1a ESRD absolute, 2.1b CKD absolute, 2.2a ESRD adjusted, and 2.2b CKD adjusted.

Table 7c. Revisions to Measures based on Technical Expert Panel (TEP) Comments

Measure Set 1. Quality Measures Using Only Enrollment and Prescription Drug Event (PDE) Data
Domain 3: Disease Specific Therapy
3.1 Percentage of CKD beneficiaries with diabetes mellitus (DM) who have at least 1 claim for an angiotensin converting enzyme inhibitors (ACEI) and/or angiotensin receptor blockers (ARB)
1. CKD beneficiaries with DM can be defined by drug proxies, i.e. with claims for phosphate binders or vitamin D analogs and hypoglycemic agents including insulin. 2. Definition of chronic or persistent therapy does not need to be 180 days; 90 days is sufficient and the 90 days do not need to be consecutive. 3. Claims that are excluded from the numerator (<90 days) should also be excluded from the denominator, otherwise the ratio would be understated. 4. This measure can be clinically supported absent blood pressure measurement or ICD-9 for hypertension because of high prevalence of hypertension among CKD beneficiaries (>80%) and the renal-protective effect of the ACEI/ARB.
3.2a Percentage of CKD beneficiaries (Stages 4-5 pre-dialysis) who have claims for calcitriol, doxercalciferol, or paricalcitol
1. Absent staging data from PDE claims, CKD can be defined by drug proxy; it should not be specified in terms of stages of CKD. 2. Since vitamin D analog is being used as the drug proxy, it cannot be measured in the numerator. The denominator population will only include those on phosphate binders to avoid circularity.
3.4 Percentage of ESRD (dialysis) patients with at least 1 claim for a Part D drug
1. Renumber to be consecutive. 2. Should also calculate a rate for ESRD patients who have no claims for Part D drugs, i.e. drugs needed by this population are not adequately covered by Part D.
3.5 Percentage of CKD beneficiaries with at least 1 claim for a Part D drug
1. Renumber to be consecutive. 2. Since CKD beneficiaries are identified by drug proxy, the measure should be re-phrased as “more than 1 claim for a Part D drug.”
3.10a Percentage of CKD beneficiaries with claims for thiazide diuretics, but no loop diuretics
3.10b Percentage of ESRD (dialysis) patients with claims for thiazide diuretics, but no loop diuretics
1. CKD stage 3 beneficiaries can benefit from thiazide diuretics. Without staging information, measure 3.10a is not meaningful. It should be deferred to phase 2 when ICD-9 codes for staging become available. 2. Thiazide diuretics are not effective for ESRD (dialysis) patients but they are not harmful, either. There is no utility in this measurement. 3.10b should be deleted.
3.11a Percentage of CKD beneficiaries with claims for potassium-sparing diuretics
3.11b Percentage of ESRD (transplant) patients with claims for potassium-sparing diuretics
1. Potassium-sparing diuretics have no therapeutic role for CKD beneficiaries, except for those with congestive heart failure (CHF), because of the benefits of aldosterone antagonism. Those without CHF should not be maintained with potassium sparing diuretics. This is especially important to measure because some patients may have been on a combination product containing a potassium-sparing ingredient for so long that even as their kidney function deteriorates, they remain on the drug that could have deleterious effects for them. 2. The numerator should contain both single agent and combination drugs. 3. Transplant patients will be included in the denominator through the identification of a drug proxy, i.e. phosphate binder or vitamin D analog. 4. There is no need to report for two separate populations. 5. When ICD-9 codes become available, the denominator population should be risk adjusted for staging, CHF and (liver) cirrhosis. 6. A good ratio for this measure should be low.

*Note: CKD beneficiaries are those in Stages 3, 4, and 5 (pre-dialysis) of kidney failure unless otherwise specified. ESRD patients are those receiving dialysis, but they are not kidney transplant patients, unless otherwise specified.

Table 7d. Revisions to Measures based on Technical Expert Panel (TEP) Comments

Measure Set 2. Quality Measures Requiring Additional Data
Domain 3: Disease Specific Therapy
3.2b Percentage of ESRD (dialysis) patients who have claims for calcitriol, doxercalciferol, or paricalcitol
1. Renumber so that (a) is associated with ESRD, (b) is associated with CKD. 2. Dialysis patients who receive IV vitamin D analogs have their serum calcium and phosphorus measured frequently. The disparity may be found among those on home peritoneal dialysis who may not receive IV vitamin D analogs. 3. For phase 2, this measure should include a monitoring component, i.e. monitoring of serum calcium and phosphorus. Calcium monitoring should be done within 6 months of commencement of therapy. 4. The feasibility of this measure depends on whether SIMS data can distinguish peritoneal dialysis patients from those treated at facilities.
3.3 Percentage of CKD beneficiaries with claims for bisphosphonates who have been tested for serum PTH
1. This measure should be re-phrased to exclude serum PTH so that it can be measured with PDE data. 2. Bisphosphonates should not be used to "treat" the bone disease attributable to secondary hyperparathyroidism in CKD beneficiaries. There is increasing evidence that bisphosphonates may be harmful to this population. 3. A "good" ratio should be low for this measure.
3.6a Percentage of CKD beneficiaries with a lipid profile test ordered
3.6b Percentage of CKD beneficiaries with >2 lipid profile tests ordered within 6 months or with LDL>100mg/dL and TG>200mg/dL who have PDE claims for LLD
3.6c Percentage of ESRD patients with a lipid profile test ordered
3.6d Percentage of ESRD patients with >2 lipid profile tests ordered within 6 months or with LDL>100mg/dL and TG>200mg/dL who have PDE claims for LLD
1. Although K/DOQI guideline provides for lipid management in ESRD, without lipid profile results, this measure is not grounded in strong evidence. 2. This measure should be deferred until laboratory results become available.
3.7a Percentage of CKD beneficiaries with elevated blood pressure who have claims for antihypertensive therapy
3.7b Percentage of ESRD (transplant) patients with elevated blood pressure who have claims for antihypertensive therapy
1. This measure is meaningful even without ICD-9 codes or blood pressure measurement because of the high prevalence of hypertension in this population. If the ratio of antihypertensive therapy is low for this population, intervention would be indicated. 2. Potassium sparing diuretics should be excluded from the numerator because their usage is inappropriate (unless CHF is a co-morbidity). 3. Both CKD and transplant patients should be combined in the denominator population (defined by drug proxy).
3.8a Percentage of CKD beneficiaries with elevated blood pressure who have claims for ACEI/ARB
3.8b Percentage of ESRD (transplant) patients with elevated blood pressure who have claims for ACEI/ARB
1. These 2 measures should be deleted. To clinically justify usage of ACEI/ARB in the CKD population, beneficiaries must have the presence of proteinurea because benefits of these drugs in the non-diabetic population are not strongly grounded. 2. The hyperkalemic effect of ACEI/ARB also can make this measure indefensible.
3.9a Percentage of CKD beneficiaries with elevated blood pressure who have a more than once-a-day dosage regimen of antihypertensive drugs
3.9b Percentage of ESRD (transplant) patients with elevated blood pressure who have a more than once-a-day dosage regimen of antihypertensive drugs

1. This measure is meaningful for its Hawthorne effect, even if not clinically significant. 2. Non-compliance is a problem for patients who have to take drugs several times a day. 3. Most patients can be maintained with the sustained release formulation of anti-hypertensive drugs. Providers should be aware of the benefits of once-a-day dosing. 4. This measure may be subject to criticism that long-acting formulations tend to be single source, brand products and are more costly than generic products, even if the latter requires multiple dosing.

Table 7e. Revisions to Measures based on Technical Expert Panel (TEP) Comments

Measure Set 2. Quality Measures Requiring Additional Data
Domain 4: Therapeutic Monitoring
4.1 Percentage of ESRD patients on iron supplement who have therapeutic monitoring
1. Delete. 2. Anemia management in ESRD patients is routine practice. 3. There is a CPM on anemia monitoring.
4.2 Percentage of CKD (Stages 3-5 pre-dialysis) beneficiaries who have anemia evaluation prior to treatment with erythropoiesis stimulating agents (ESA)
1. This measure is for phase 2 when laboratory results become available.
4.3a and 4.3b Percentage of CKD beneficiaries on vitamin D sterol therapy who have therapeutic monitoring
4.3c and 4.3d Percentage of ESRD patients on vitamin D sterol therapy who have therapeutic monitoring 1. Vitamin D analog therapy does require therapeutic monitoring but is not feasible for this contract. 2. Defer to phase 2 development.
*Note: CKD beneficiaries are those in Stages 3-5 (pre-dialysis) of kidney failure unless otherwise specified. ESRD patients are those receiving dialysis, but they are not kidney transplant patients, unless otherwise specified.

2.5.4. Final List of Proposed CKD/ESRD Measures

BearingPoint revised the candidate measures based on the written comments received from the TEP and CMS, as well as follow-up conversations with individual members, and submitted the final list of proposed measures on December 1, 2006. These measures were approved by CMS for development of the technical specifications.

Table 8 summarizes the revised measures for Measure Set 1 and Measure Set 2. Measure Set 1 includes a total of 23 measure ratios, of which seven are for ESRD and 16 are for CKD. Measure Set 2 includes a total of seven measure ratios, of which two are for ESRD and five are for CKD.

Table 8. Final Proposed Medication Measure for End Stage Renal Disease (ESRD) and Chronic Kidney Disease (CKD) (12/01/2006)	
Measure Description	**Numerator/Denominator**
Measure Set 1. Quality Measures Using Only Enrollment, Prescription Drug Event (PDE), and Standard Information Management System (SIMS) Data	
Patient Safety Measures	
Patient Safety Measure 1.1 **Potential Drug-Drug Interactions (DDI)** ESRD 1.1a1 Percentage of all ESRD (dialysis) patients who have PDE claims for ≥ 2 drugs with the potential to interact 1.1a2 Of ESRD (dialysis) patients who have PDE claims for ≥ 1 precipitant or object drug on the DDI list, the percentage who have ≥ 2 drugs with the potential to interact CKD 1.1b1 Percentage of all CKD (including transplant) beneficiaries who have PDE claims for ≥ 2 drugs with the potential to interact 1.1b2 Of CKD (including transplant) beneficiaries who have claims for ≥ 1 precipitant or object drug on the DDI list, the percentage who have ≥ 2 drugs with the potential to interact	ESRD Denominator 1.1a1 Statement: ESRD (dialysis) patients who have PDE claims for any Part D drugs during the measurement period Denominator 1.1a2 Statement: ESRD (dialysis) patients who have PDE claims for any of the object or precipitant drugs during the measurement period Numerators 1.1a1 and 1.1a2 Statement: ESRD (dialysis) patients in the denominator with ≥ 1 potential DDI in PDE claims during the measurement period CKD Denominator 1.1b1 Statement: CKD (including transplant) beneficiaries who have PDE claims for any Part D drug during the measurement period Denominator 1.1b2 Statement: CKD (including transplant) beneficiaries who have PDE claims for any of the object or precipitant drugs during the measurement period Numerators 1.1b1 and 1.1b2 Statement: CKD (including transplant) beneficiaries in the denominator with ≥ 1 potential DDI in PDE claims during the measurement period
Patient Safety Measure 1.2 **ESRD: Drugs to be Avoided** 1.2a: Percentage of ESRD (dialysis) patients with drugs to be avoided. **CKD: Drugs Requiring Appropriate Dosing** 1.2b: Percentage of CKD (including transplant) beneficiaries with drugs requiring appropriate dosing	ESRD Denominator 1.2a Statement: ESRD (dialysis) patients with ≥ 1 PDE claim for Part D drugs during the measurement period Numerator 1.2a Statement: ESRD (dialysis) patients in the denominator with ≥ 1 PDE claim for a drug to be avoided CKD Denominator 1.2b Statement: CKD (including transplant) beneficiaries with ≥ 1 PDE claim for Part D covered drugs during the measurement period Numerator 1.2b Statement: CKD (including transplant) beneficiaries in the denominator with ≥ 1 PDE claim for drugs requiring appropriate dosing

Table 8. Final Proposed Medication Measure for End Stage Renal Disease (ESRD) and Chronic Kidney Disease (CKD) (12/01/2006)	
Measure Description	**Numerator/Denominator**
Pharmacoeconomic Measures	
Pharmacoeconomic Measure 2.1 **Absolute Generic Utilization Ratios** ESRD 2.1a Percentage of generic utilization (absolute) for ESRD (dialysis) patients CKD 2.1b Percentage of generic utilization (absolute) for CKD (including transplant) beneficiaries	ESRD Denominator 2.1a Statement: Total number of PDE claims for Part D covered drugs for ESRD (dialysis) patients during the measurement period Numerator 2.1a Statement**:** Number of PDE claims in the denominator that are for generic formulations during the measurement period CKD Denominator 2.1b Statement: Total number of PDE claims for Part D covered drugs for CKD beneficiaries during the measurement period Numerator 2.1b Statement: Number of PDE claims in the denominator that are for generic formulations during the measurement period
Pharmacoeconomic Measure 2.2 **Adjusted Generic Utilization Ratios** ESRD 2.2a Percentage of generic utilization (adjusted) for ESRD (dialysis) patients CKD 2.2b Percentage of generic utilization (adjusted) for CKD (including transplant) beneficiaries	ESRD Denominator 2.2a Statement: Total number of PDE claims for Part D covered drugs for ESRD (dialysis) patients that are generic or have available generic equivalent formulations during the measurement period Numerator 2.2a Statement: Number of PDE claims in the denominator that are for generic formulations during the measurement period CKD Denominator 2.2b Statement: Total number of PDE claims for Part D covered drugs for CKD beneficiaries that are generic or have available generic equivalent formulations during the measurement period Numerator 2.2b Statement: Number of PDE claims in the denominator that are for generic formulations during the measurement period

Table 8. Final Proposed Medication Measure for End Stage Renal Disease (ESRD) and Chronic Kidney Disease (CKD) (12/01/2006)	
Measure Description	**Numerator/Denominator**
Disease Specific Therapy Measures	
Disease Specific Therapy Measure 3.1 **CKD DM and ACEI/ARB Therapy** Percentage of CKD (including transplant) beneficiaries with diabetes mellitus (DM) who have claims for ≥ 90 days supply of ACEI and/or ARB drugs 3.1A Percentage of diabetic Part D enrollees who had ACEI only 3.1B Percentage of diabetic Part D enrollees who had ARB only 3.1C Percentage of diabetic Part D enrollees who had ACEI switching to ARB only once 3.1D Percentage of diabetic Part D enrollees who had ARB switching to ACEI only once 3.1E Percentage of diabetic Part D enrollees who had multiple switches between ARB and ACEI	Denominator 3.1 Statement: The number of diabetic CKD (including transplant) beneficiaries during the measurement period Numerator 3.1 Statement: CKD (including transplant) beneficiaries in the denominator with PDE claims for ≥ 90 days supply of ACEI/ARB Numerator 3.1a: Of those in numerator 3.1, the number who have claims for ACEI only Numerator 3.1b: Of those in numerator 3.1, the number who have claims for ARB only Numerator 3.1c: Of those in numerator 3.1, the number who have one switch—from ACEI to ARB Numerator 3.1d: Of those in numerator 3.1, the number who have one switch—from ARB to ACEI Numerator 3.1e: The number of remaining beneficiaries in numerator 3.1 who are not allocated to numerators 3.1a, 3.1b, 3.1c, and 3.1d
Disease Specific Therapy Measure 3.2 **CKD and Bisphosphonate Therapy** Percentage of CKD (including transplant) beneficiaries who have claims for ≥ 90 days supply for bisphosphonates	Denominator 3.2 Statement: CKD (including transplant) beneficiaries with ≥ 1 PDE claim for Part D drugs during the measurement period Numerator 3.2 Statement: CKD (including transplant) beneficiaries in the denominator who have claims for ≥ 90 days supply for bisphosphonates during the measurement period
Disease Specific Therapy Measure 3.3 **CKD/ESRD and Part D Drugs** ESRD 3.3a1: Percentage of ESRD (dialysis) patients who have ≥ 1 claim for a Part D drug 3.3a2: Percentage of ESRD (dialysis) patients who have no claims for Part D drugs CKD 3.3b1: Percentage of CKD (including transplant) beneficiaries who have ≥ 1 claim for a Part D drug (other than Part D drugs used to define CKD) 3.3b2: Percentage of CKD (including transplant) beneficiaries who have no claims for Part D drugs (other than Part D drugs used to define CKD)	ESRD Denominators 3.3a1 and 3.3a2 Statement: ESRD (dialysis) population Numerator 3.3a1 Statement: ESRD (dialysis) patients in the denominator with ≥ 1 Part D claim during the measurement period Numerator 3.3a2 Statement: ESRD (dialysis) patients in the denominator with no PDE claims for Part D covered drugs during the measurement period CKD Denominators 3.3b1 and 3.3b2 Statement: CKD (including transplant) population Numerator 3.3b1 Statement: CKD (including transplant) beneficiaries in the denominator with at least 1 Part D covered drug (other than the drug used to define CKD) in PDE claims during measurement period Numerator 3.3b2 Statement: CKD (including transplant) beneficiaries in the denominator with no claims during measurement period for Part D covered drugs (other than the drug used to define CKD) during the measurement period

Table 8. Final Proposed Medication Measure for End Stage Renal Disease (ESRD) and Chronic Kidney Disease (CKD) (12/01/2006)	
Measure Description	**Numerator/Denominator**
Disease Specific Therapy Measure 3.4 **CKD and Antihypertensive Therapy** Percentage of CKD (including transplant patients) beneficiaries who have no claims for antihypertensive therapy (excluding potassium-sparing diuretics)	Denominator 3.4 Statement: CKD (including ESRD transplant) beneficiaries during measurement period Numerator 3.4 Statement: CKD (including transplant patients) beneficiaries in the denominator with PDE claims for any antihypertensive therapy during measurement period
Disease Specific Therapy Measure 3.5 **CKD and Antihypertensive Therapy – Dosing Regimen** Percentage of CKD (including transplant) beneficiaries who have a more than once-a-day dosage regimen of antihypertensive drugs	This measure was re-classified to Measure Set 2 due to the need to identify CKD Stages 1-3 using ICD-9-CM diagnosis codes.
Disease Specific Therapy Measure 3.6 **CKD and Potassium-Sparing Diuretic Therapy** Percentage of CKD (including transplant) beneficiaries who have claims for ≥ 90 days supply for potassium-sparing diuretics	Denominator 3.6 Statement: CKD (including transplant) population Numerator 3.6 Statement: CKD (including transplant) beneficiaries in the denominator with claims for ≥ 90 days supply of potassium-sparing diuretics during measurement period

Table 8. Final Proposed Medication Measure for End Stage Renal Disease (ESRD) and Chronic Kidney Disease (CKD) - (12/01/2006)	
Measure Description	**Numerator/Denominator**
Measure Set 2. Quality Measures Requiring Additional Data	
Disease Specific Therapy Measures	
Disease Specific Therapy Measure 3.5 **CKD and Antihypertensive Therapy Measure** Percentage of CKD (Stages 1-3 including transplant) beneficiaries with a more than once-a-day dosage regimen of antihypertensive drugs	Denominator 3.5 Statement: CKD (Stages 1-3, including transplant) hypertensive beneficiaries with Part D claims for ≥ 8 medications of which at least 2 are for unique hypertension medications during the measurement period Numerator 3.5 Statement: Beneficiaries in the denominator with Part D claims for any antihypertensive drugs requiring more than a once-a-day dosing during measurement period
Disease Specific Therapy Measure 3.7 **CKD and Thiazide Therapy Measure** Percentage of CKD (Stages 4, 5 including transplant) beneficiaries with claims for thiazide but no loop diuretics	Denominator 3.7 Statement: CKD (Stages 4-5 including transplant) beneficiaries with at least one Part D claim during measurement period Numerator 3.7 Statement: Number of beneficiaries in the denominator with at least one Part D claim for thiazide diuretics, but no claims for loop diuretics during the measurement period
Therapeutic Monitoring Measures	
Therapeutic Monitoring Measure 4.1 **CKD and Anemia Evaluation Measure** Percentage of CKD (Stages 3-5 including transplant) beneficiaries with anemia evaluation prior to treatment with erythropoiesis stimulating agents (ESA)	Denominator 4.1 Statement: CKD3-5 (including transplant) beneficiaries with Part D claims for ESA therapy during measurement period Numerator 4.1 Statement: CKD beneficiaries in the denominator with at least one outpatient or physician claim with a CPT code for anemia evaluation where the day of service (DOS) is before the earliest Part D claim DOS for ESA in the measurement period
Therapeutic Monitoring Measure 4.2 **Vitamin D Sterol Therapy Monitoring** ESRD Percentage of ESRD (dialysis) patients beneficiaries on vitamin D sterol therapy with therapeutic monitoring 4.2a1 Percentage of ESRD (dialysis) patients on vitamin D sterol therapy with therapeutic monitoring within 6 months prior to initial vitamin D sterol therapy 4.2a2: Percentage of ESRD (dialysis) patients on vitamin D sterol therapy with therapeutic monitoring within 6 months after initial vitamin D sterol therapy	Denominators 4.2a1 & 4.2a2 Statement: ESRD (dialysis) patients with at least one claim for intravenous paricalcitol, calcitriol, or doxercalciferol or at least 90 days supply of an oral vitamin D sterol during measurement period Numerator 4.2a1 Statement: Patients in the denominator with claims for serum calcium, serum phosphorus, iPTH within 6 months *prior* to initiation of intravenous or oral vitamin D sterol during measurement period Numerator 4.2a2 Statement: Patients in the denominator with claims for serum calcium, serum phosphorus, (1-84) PTH or iPTH within 6 months *after* initiation of intravenous or oral vitamin D sterol during measurement period

Table 8. Final Proposed Medication Measure for End Stage Renal Disease (ESRD) and Chronic Kidney Disease (CKD) - (12/01/2006)	
Measure Description	**Numerator/Denominator**
CKD Percentage of CKD (Stages 3-5 including transplant) beneficiaries on vitamin D sterol therapy with therapeutic monitoring 4.2b1 Percentage of CKD beneficiaries (Stages 3-5 including transplant) on vitamin D sterol therapy with therapeutic monitoring within 6 months prior to initial vitamin D sterol therapy 4.2b2 Percentage of CKD beneficiaries (Stages 3-5 including transplant) on vitamin D sterol therapy with therapeutic monitoring within 6 months after initial vitamin D sterol therapy	Denominators 4.2b1 & 4.2b2 Statement: CKD3-5 (including transplant) beneficiaries with claims for at least 90 days supply of oral vitamin D sterol during measurement period Numerator 4.2b1 Statement: Beneficiaries in the denominator with claims for serum calcium, serum phosphorus, iPTH within 6 months *prior* to initiation of intravenous or oral vitamin D sterol therapy during measurement period Numerator 4.2b2 Statement: Beneficiaries in the denominator with tests for serum calcium, serum phosphorus, (1-84) PTH or iPTH ordered within 6 months *after* initiation of intravenous or oral vitamin D sterol therapy during measurement period

Table 9 shows the post-TEP revised measures with new measures numbers.

Table 9. Post- TEP Revised Measures with New Measure Numbers

Measure	Modifications Summary (7/2006 – 12/2006)	Measure Number	
		Original	Revised
Measure Set 1 (Uses only Part D and SIMS data)			
Patient Safety Measures			
ESRD/CKD Drug-Drug Interaction (1.1a1, 1.1a2, 1.1b1, 1.1b2)	Split into four measures, reporting CKD and ESRD populations separately. Each population has two separate denominators.	1.1	1.1
ESRD/CKD Drugs Requiring Caution (1.2a, 1.2b)	The phrase "Drugs Requiring Caution" (DRC) was changed to "drugs to be avoided" and "drugs requiring appropriate dosing" for ESRD and CKD, respectively.	1.2, 1.3	1.2
Pharmacoeconomic Measures			
ESRD/CKD Generic Utilization Ratios (Absolute) (2.1a, 2.1b)	Rephrased to refer to absolute and adjusted ratios.	2.1	2.1
ESRD/CKD Generic Utilization Ratios (Adjusted) (2.2a, 2.2b)		2.2	2.2
Disease Specific Therapy Measures			
CKD DM and ACEI/ARB Therapy (3.1)	Rephrased and modified to reflect the definition of chronic or persistent therapy	3.1	3.1
CKD and Bisphosphonate Therapy (3.2)	Rephrased to exclude PTH so that it can be calculated with Part D data.	3.3	3.2
ESRD/CKD and Part D Drugs (3.3a, 3.3b)	Split into two measures to show patients with and without Part D claims	3.4, 3.5	3.3
CKD and Antihypertensive Therapy (3.4)	Rephrased to combine CKD and transplant populations	3.7	3.4
CKD and Multiple Dosage Antihypertensive Therapy (3.5)	Reclassified to Measure Set 2	3.9	3.5
CKD and Potassium-Sparing Diuretic Therapy (3.6)	Rephrased to combine CKD and transplant populations	3.11	3.6
Measure Set 2 (Uses Part D data integrated with other data, e.g., ICD-9-CM and CPT codes)			
Disease Specific Therapy Measures			
CKD and Thiazide Therapy (3.7)	Deferred to Measure Set 2	3.10	3.7
Therapeutic Monitoring Measures			
CKD and Anemia Evaluation (4.1)	No change	4.2	4.1
CKD and Monitoring Vitamin D Sterol Therapy (4.2a1, 4.2a2, 4.2b1, 4.2b2)	Deferred to Measure Set 2	4.3	4.2
Deleted Measures			
Use of calcitriol, doxercalciferol or paricalcitol among CKD/ESRD		3.2	
Lipid management of ESRD/CKD who have abnormal lipid profiles		3.6	
Use of ACEI/ARB in ESRD/CKD who have high blood pressure		3.8	
Use of thiazides in ESRD		3.10	
Anemia monitoring ESRD on iron supplement		4.1	

2.6. TECHNICAL SPECIFICATIONS

The technical specifications for Measure Sets 1 and 2 were developed but not formative tested. This section provides an overview of these technical specifications. Appendix L shows the complete Measure Set 1 Technical Specifications and its appendix, and Appendix M shows the Measure Set 2 Technical Specifications and appendix.

2.6.1. Purpose and Methods

The purpose of developing the technical specifications was to define the algorithms to calculate each measure's numerator and denominator. The following modifications to the measures were made during the development of the technical specifications:

1. Terminology in measure statements and denominator/numerator statements was standardized to make consistent, e.g., "at least 1" was standardized to "≥ 1"; "who had" was standardized to "with"; "claim for a Part D drug" was standardized to "Part D claim".
2. Measure 3.1 was refined and added to Measure Set 2. Refinements included using ICD-9-CM diagnosis codes to identify CKD Stages 1-5, diabetes, and hypertension.
3. Measure 3.5 was re-classified to Measure Set 2 due to the need to identify beneficiaries with CKD Stages 1-3.
4. A TEP member recommended that the denominator of Measure 3.7 be changed from CKD beneficiaries with "at least one claim for a thiazide" to "≥ 90 days supply of a thiazide".

Measure Set 1 includes 18 measures that require Part D enrollment data, Part D drug claims data, and SIMS data. One of the 18 measures is sub-divided into five ratios. Measure Set 2 includes eight measures that require databases with ICD-9-CM diagnosis codes, CPT procedure codes, and HCPCS codes for drugs not covered by Part D in addition to Part D enrollment and drug claims data and SIMS data. One of the eight measures is sub-divided into five ratios.

Measure 3.1 is included in both Measure Sets 1 and 2 because the original definition used drug proxies to identify diabetes. CMS later requested that this measure be further refined using ICD-9-CM codes to identify diabetic hypertensive beneficiaries. This measure was also refined to include CKD stages 1-5 because the use of ACEIs/ARBs in diabetic hypertensive CKD beneficiaries applies to all stages. Using drug proxies to identify CKD does not capture CKD Stages 1 and 2. As in Measure Set 1, this measure is classified into five additional ratios.

The technical specifications include the definition of the measures, the rationale, the definition of terms, the numerator statement and algorithm, the denominator statement and algorithm, and flow diagrams of the algorithms. These specifications were developed without access to the datasets, nor were the specifications tested and refined. Therefore, the specifications may require modification to accommodate the properties of data actually used to calculate the measures.

Table 10 lists the final measures for both Measure Set 1 and Measure Set 2.

Table 10. CKD/ESRD Medication Measures for Quality Improvement Organizations (QIOs) and End Stage Renal Disease (ESRD) Networks	
Measure Set 1. CKD/ESRD Quality Measures Using Only Part D Enrollment, Part D Claims, and SIMS Data	
Domain 1: Patient Safety Measures	**Count**
Drug-Drug Interaction	
1.1a1 Percentage of all ESRD (dialysis) patients with ≥ 2 drugs having the potential to interact	1
1.1a2 Among ESRD (dialysis) patients with ≥ 1 object or precipitant drug, percentage with ≥ 2 drugs having the potential to interact	2
1.1b1 Percentage of all CKD (including transplant) beneficiaries with ≥ 2 drugs having the potential to interact	3
1.1b2 Among CKD (including transplant) beneficiaries with ≥ 1 object or precipitant drug, percentage with ≥ 2 drugs having the potential to interact	4
Drugs Requiring Caution	
1.2a Percentage of ESRD (dialysis) patients with drugs to be avoided	5
1.2b Percentage of CKD (including transplant) beneficiaries with drugs requiring appropriate dosing	6
Domain 2: Pharmacoeconomic Measures	
Generic Utilization Ratios	
2.1a Percentage of generic utilization (absolute) for ESRD (dialysis) patients	7
2.1b Percentage of generic utilization (absolute) for CKD (including transplant) beneficiaries	8
2.2a Percentage of generic utilization (adjusted) for ESRD (dialysis) patients	9
2.2b Percentage of generic utilization (adjusted) for CKD (including transplant) beneficiaries	10
Domain 3: Disease Specific Therapy Measures	
CKD Diabetes Mellitus and ACEI/ARB Therapy	
3.1 Percentage of CKD (including transplant) beneficiaries with diabetes mellitus (DM) with ≥ 90 days supply of ACEI and/or ARB drugs This is also classified into the following: Percentage of diabetic CKD (including transplant) beneficiaries with:	11
3.1a ACEI only	12
3.1b ARB only	13
3.1c ACEI switching to ARB only	14
3.1d ARB switching to ACEI only	15
3.1e Multiple switches between ARB and ACEI	16
CKD and Bisphosphonate Therapy	
3.2 Percentage of CKD (including transplant) beneficiaries with ≥ 90 days supply of bisphosphonates	17
CKD/ESRD and Part D Drugs	
3.3a1 Percentage of ESRD (dialysis) patients with ≥ 1 Part D claim	18
3.3a2 Percentage of ESRD (dialysis) patients with no Part D claims	19
3.3b1 Percentage of CKD (including transplant) beneficiaries with ≥ 1 Part D claim (other than proxy drugs used to define CKD)	20
3.3b2 Percentage of CKD (including transplant) beneficiaries with no Part D claims (other than proxy drugs used to define CKD)	21
CKD and Antihypertensive Therapy	
3.4 Percentage of CKD (including transplant) beneficiaries with ≥ 90 days supply of antihypertensive therapy (excluding potassium-sparing diuretics)	22
CKD and Potassium-Sparing Diuretic Therapy	
3.6 Percentage of CKD (including transplant) beneficiaries with ≥ 90 days supply of potassium-sparing diuretics	23
Measure Set 2. CKD/ESRD Quality Measures Using Additional Data*	
Domain 3: Disease Specific Therapy Measures	
CKD Diabetes Mellitus and ACEI/ARB Therapy	
3.1** Percentage of CKD (Stages 1-5 including transplant) beneficiaries with diabetes mellitus (DM) and hypertension (HTN) with ≥ 90 days supply of ACEI and/or ARB drugs	1
This is also classified into the following: Percentage of diabetic hypertensive CKD (Stages 1-5 including transplant) beneficiaries with:	

Table 10. CKD/ESRD Medication Measures for Quality Improvement Organizations (QIOs) and End Stage Renal Disease (ESRD) Networks	
3.1a ACEI only	2
3.1b ARB only	3
3.1c ACEI switching to ARB only	4
3.1d ARB switching to ACEI only	5
3.1e Multiple switches between ARB and ACEI	6
CKD and Antihypertensive Therapy	
3.5 Percentage of CKD (Stages 1-3 including transplant) hypertensive beneficiaries with a more than once-a-day dosage regimen of antihypertensive drugs	7
CKD and Thiazide Therapy	
3.7 Percentage of CKD (Stages 4-5 including transplant) beneficiaries with ≥ 90 days supply of thiazide diuretics, but no loop diuretics	8
Domain 4: Therapeutic Monitoring Measures	
CKD and Anemia Evaluation	
4.1 Percentage of CKD (Stages 3-5 including transplant) beneficiaries with an anemia evaluation prior to treatment with erythropoiesis stimulating agents (ESA)	9
CKD/ESRD and Vitamin D Sterol Therapy Monitoring	
4.2a1 Percentage of ESRD (dialysis) patients on vitamin D sterol therapy with therapeutic monitoring within 6 months *prior* to initial vitamin D sterol therapy	10
4.2a2 Percentage of ESRD (dialysis) patients on vitamin D sterol therapy with therapeutic monitoring within 6 months *after* initial vitamin D sterol therapy	11
4.2b1 Percentage of CKD (Stages 3-5 including transplant) beneficiaries on vitamin D sterol therapy with therapeutic monitoring within 6 months *prior* to initial vitamin D sterol therapy	12
4.2b2 Percentage of CKD (Stages 3-5 including transplant) beneficiaries on vitamin D sterol therapy with therapeutic monitoring within 6 months *after* initial vitamin D sterol therapy	13

*Note: Shading indicates measures requiring additional datasets.
** Measure 3.1 is also included in Measure Set 1 because the original definition used drug proxies to identify CKD and diabetes. This measure was further refined using ICD-9-CM codes to identify diabetic hypertensive CKD (Stages 1-5) beneficiaries.

Table 11 shows the final numerator and denominator statements as of May 25, 2007.

Table 11. Final Proposed Medication Measure for End Stage Renal Disease (ESRD) and Chronic Kidney Disease (CKD) - (5/25/07)	
Measure Description	**Numerator/Denominator**
Measure Set 1. Quality Measures Using Only Part D and SIMS Data	
Patient Safety Measures	
Patient Safety Measure 1.1 Potential Drug-Drug Interactions (DDI) ESRD 1.1a1 Percentage of all ESRD (dialysis) patients with ≥ 2 drugs having the potential to interact 1.1a2 Among ESRD (dialysis) patients with ≥ 1 object or precipitant drug, percentage with ≥2 drugs having the potential to interact CKD 1.1b1 Percentage of all CKD (including transplant) beneficiaries with ≥2 drugs having the potential to interact 1.1b2 Among CKD (including transplant) beneficiaries with for ≥1 object or precipitant drug, percentage with ≥2 drugs having the potential to interact	ESRD Denominator 1.1a1 Statement: ESRD (dialysis) patients with claims for any Part D drugs during the measurement period. Denominator 1.1a2 Statement: ESRD (dialysis) patients with claims for any of the object or precipitant drugs during the measurement period. Numerator 1.1a1 and 1.1a2 Statement: ESRD (dialysis) patients in the denominator with ≥ 1 potential DDI (≥ 2 drugs having the potential to interact) during the measurement period. CKD Denominator 1.1b1 Statement: CKD (including transplant) beneficiaries with claims for any Part D drug during the measurement period Denominator 1.1b2 Statement: CKD (including transplant) beneficiaries with Part D claims for any of the object or precipitant drugs during the measurement period Numerator 1.1b1 and 1.1b2 Statement: CKD (including transplant) beneficiaries in the denominator with ≥ 1 potential DDI (≥2 drugs having the potential to interact) during measurement period.
Patient Safety Measure 1.2 ESRD: Drugs to be Avoided 1.2a Percentage of ESRD (dialysis) patients with drugs to be avoided. CKD: Drugs Requiring Appropriate Dosing 1.2b Percentage of CKD (including transplant) beneficiaries with drugs requiring appropriate dosing.	ESRD Denominator 1.2a Statement: ESRD (dialysis) patients with ≥ 1 Part D claim during the measurement period Numerator 1.2a Statement: ESRD (dialysis) patients in the denominator with ≥ 1 Part D claim for a drug to be avoided. CKD Denominator 1.2b Statement: CKD (including transplant) beneficiaries with ≥ 1 Part D claim for Part D covered drugs during the measurement period Numerator 1.2b Statement: CKD (including transplant) beneficiaries in the denominator with ≥ 1 Part D claim for drugs requiring appropriate dosing

Table 11. Final Proposed Medication Measure for End Stage Renal Disease (ESRD) and Chronic Kidney Disease (CKD) - (5/25/07)

Measure Description	Numerator/Denominator
Measure Set 1. Quality Measures Using Only Part D and SIMS Data	
Pharmacoeconomic Measures	
Pharmacoeconomic Measure 2.1 **Absolute Generic Utilization Ratios** ESRD 2.1a Percentage of generic utilization (absolute) for ESRD (dialysis) patients CKD 2.1b Percentage of generic utilization (absolute) for CKD (including transplant) beneficiaries	ESRD Denominator 2.1a Statement: Total number of Part D claims for ESRD (dialysis) patients during the measurement period Numerator 2.1a Statement: Part D claims in the denominator that are for generic formulations CKD Denominator 2.1b Statement: Total number of Part D claims for CKD (including transplant) beneficiaries during the measurement period Numerator 2.1b Statement: Part D claims in the denominator that are for generic formulations
Pharmacoeconomic Measure 2.2 **Adjusted Generic Utilization Ratios** ESRD 2.2a Percentage of generic utilization (adjusted) for ESRD (dialysis) patients CKD 2.2b Percentage of generic utilization (adjusted) for CKD (including transplant) beneficiaries	ESRD Denominator 2.2a Statement: Total number of Part D claims for ESRD (dialysis) patients that are generic or have available generic equivalent formulations during the measurement period Numerator 2.2a Statement: Part D claims in the denominator that are for generic formulations CKD Denominator 2.2b Statement: Total number of Part D claims for CKD (including transplant) beneficiaries that are generic or have available generic equivalent formulations during the measurement period Numerator 2.2b Statement: Part D claims in the denominator that are for generic formulations
Disease Specific Therapy Measures	
Disease Specific Therapy Measure 3.1 **CKD DM and ACEI/ARB Therapy** Percentage of CKD (including transplant) beneficiaries with diabetes mellitus (DM) with ≥ 90 days supply of ACEI and/or ARB drugs	Denominator 3.1 Statement: The number of diabetic CKD (including transplant) beneficiaries during the measurement period. Numerator 3.1 Statement: CKD (including transplant) beneficiaries in the denominator with ≥90 days supply of ACEI/ARB Numerator 3.1a: Of those in numerator 3.1, the number with claims for ACEI only Numerator 3.1b: Of those in numerator 3.1, the number with claims for ARB only Numerator 3.1c: Of those in numerator 3.1, the number with one switch – from ACEI to ARB Numerator 3.1d: Of those in numerator 3.1, the number with one switch – from ARB to ACEI Numerator 3.1e: The number of remaining beneficiaries in numerator 3.1 who are not allocated to numerators 3.1A, 3.1B, 3.1C, and 3.1D.

Table 11. Final Proposed Medication Measure for End Stage Renal Disease (ESRD) and Chronic Kidney Disease (CKD) - (5/25/07)

Measure Description	Numerator/Denominator
Measure Set 1. Quality Measures Using Only Part D and SIMS Data	
Disease Specific Therapy Measure 3.2 **CKD and Bisphosphonate Therapy** Percentage of CKD (including transplant) beneficiaries with ≥ 90 days supply of bisphosphonates	**Denominator 3.2 Statement**: CKD (including transplant) beneficiaries with ≥1 Part D claim during the measurement period Numerator 3.2 Statement: CKD (including transplant) beneficiaries in the denominator with ≥ 90 days supply of bisphosphonates.
Disease Specific Therapy Measure 3.3 **CKD/ESRD and Part D Drugs** ESRD 3.3a1: Percentage of ESRD (dialysis) patients with ≥ 1 Part D claim 3.3a2: Percentage of ESRD (dialysis) patients with no Part D claim CKD 3.3a1: Percentage of ESRD (dialysis) patients with ≥1 Part D claim 3.3a2: Percentage of ESRD (dialysis) patients with no Part D claim	ESRD Denominators 3.3a1 and 3.3a2 Statement: ESRD (dialysis) population Numerator 3.3a1 Statement: ESRD (dialysis) patients in the denominator with ≥ 1 Part D claim Numerator 3.3a2 Statement: ESRD (dialysis) patients in the denominator with no Part D claim during the measurement period CKD Denominators 3.3b1 and 3.3b2 Statement: CKD (including transplant) population Numerator 3.3b1 Statement: CKD (including transplant) beneficiaries in the denominator with ≥1 Part D claim (other than proxy drugs used to define CKD) during measurement period Numerator 3.3b2 Statement: CKD (including transplant) beneficiaries in the denominator with no Part D claim during measurement period (other than proxy drugs used to define CKD)
Disease Specific Therapy Measure 3.4 **CKD and Antihypertensive Therapy** Percentage of CKD (including transplant) beneficiaries with ≥ 90 days supply of antihypertensive therapy (excluding potassium-sparing diuretics)	Denominator 3.4 Statement: The CKD (including transplant) population with ≥ 1 drug claim Numerator 3.4 Statement: CKD (including transplant) beneficiaries in the denominator with ≥ 90 days supply over all antihypertensive therapies (excluding potassium-sparing diuretics) during measurement period
Disease Specific Therapy Measure 3.6 **CKD and Potassium-Sparing Diuretic Therapy** Percentage of CKD (including transplant) beneficiaries with ≥ 90 days supply of potassium-sparing diuretics	Denominator 3.6 Statement: CKD (including transplant) population Numerator 3.6 Statement: CKD (including transplant) beneficiaries in the denominator with ≥ 90 days supply of potassium-sparing diuretics during measurement period

Table 11. Final Proposed Medication Measure for End Stage Renal Disease (ESRD) and Chronic Kidney Disease (CKD) - (5/25/2007)	
Measure Description	**Numerator/Denominator**
Measure Set 2. Quality Measures Requiring Additional Data	
Disease Specific Therapy Measures	
Disease Specific Therapy Measure 3.1 **CKD DM and ACEI/ARB Therapy** Percentage of CKD (Stages 1-5 including transplant) beneficiaries with diabetes mellitus (DM) and hypertension (HTN) with ≥ 90 days supply of ACEI and/or ARB drugs	Denominator 3.1 Statement: Diabetic hypertensive CKD1-5 (including transplant) beneficiaries during the measurement period. Numerator 3.1 Statement: Identify beneficiaries in the denominator with ≥90 days supply of ACEIs and/or ARBs. Numerator 3.1A: Of those in numerator 3.1, the number with claims for ACEI only Numerator 3.1B: Of those in numerator 3.1, the number with claims for ARB only Numerator 3.1C: Of those in numerator 3.1, the number with one switch – from ACEI to ARB Numerator 3.1D: Of those in numerator 3.1, the number with one switch – from ARB to ACEI Numerator 3.1E: The number of remaining beneficiaries in numerator 3.1 who are not allocated to numerators 3.1A, 3.1B, 3.1C, and 3.1D.
Disease Specific Therapy Measure 3.5 **CKD and Antihypertensive Therapy Measure** Percentage of hypertensive CKD (Stages 1-3 including transplant) beneficiaries with a more than once-a-day dosage regimen of antihypertensive drugs	Denominator 3.5 Statement: CKD (Stages 1-3, including transplant) hypertensive beneficiaries with ≥ 8 medications of which at least 2 are for unique hypertension medications during the measurement period Numerator 3.5 Statement: Beneficiaries in the denominator with Part D claims for any antihypertensive drugs requiring more than a once-a-day dosing during measurement period
Disease Specific Therapy Measure 3.7 **CKD and Thiazide Therapy Measure** Percentage of CKD (Stages 4-5 including transplant) beneficiaries with ≥90 days supply of thiazides, but no loop diuretics	Denominator 3.7 Statement: CKD (Stages 4-5 including transplant) beneficiaries with ≥90 days supply of thiazide diuretics during measurement period. Numerator 3.7 Statement: Number of beneficiaries in the denominator with no claims for loop diuretics during the measurement period
Therapeutic Monitoring Measures	
Therapeutic Monitoring Measure 4.1 **CKD and Anemia Evaluation Measure** Percentage of CKD (Stages 3-5 including transplant) beneficiaries with anemia evaluation prior to treatment with Part D erythropoiesis stimulating agents (ESA)	Denominator 4.1 Statement: CKD3-5 (including transplant) beneficiaries ESA therapy during measurement period. Numerator 4.1 Statement: CKD beneficiaries in the denominator with at least one outpatient or physician claim with a CPT code for anemia evaluation where the day of service (DOS) is before the earliest Part D claim DOS for ESA in the measurement period

Table 11. Final Proposed Medication Measure for End Stage Renal Disease (ESRD) and Chronic Kidney Disease (CKD) - (5/25/2007)	
Measure Description	**Numerator/Denominator**
Measure Set 2. Quality Measures Requiring Additional Data	
Therapeutic Monitoring Measure 4.2 **Vitamin D Sterol Therapy Monitoring** ESRD 4.2a1 Percentage of ESRD (dialysis) patients on vitamin D sterol therapy with therapeutic monitoring within 6 months prior to initial vitamin D sterol therapy 4.2a2: Percentage of ESRD (dialysis) patients on vitamin D sterol therapy with therapeutic monitoring within 6 months after initial vitamin D sterol therapy CKD 4.2b1 Percentage of CKD beneficiaries (Stages 3-5 including transplant) on vitamin D sterol therapy with therapeutic monitoring within 6 months prior to initial vitamin D sterol therapy 4.2b2 Percentage of CKD beneficiaries (Stages 3-5 including transplant) on vitamin D sterol therapy with therapeutic monitoring within 6 months after initial vitamin D sterol therapy	ESRD Denominators 4.2a1 & 4.2a2 Statement: ESRD (dialysis) patients with ≥ 1 claim for intravenous paricalcitol, calcitriol, or doxercalciferol or ≥ 90 days supply of an oral vitamin D sterol during measurement period Numerator 4.2a1 Statement: Patients in the denominator with claims for serum calcium, serum phosphorus, iPTH within 6 months *prior* to initiation of intravenous or oral vitamin D sterol during measurement period Numerator 4.2a2 Statement: Patients in the denominator with claims for serum calcium, serum phosphorus, (1-84) PTH or iPTH within 6 months *after* initiation of intravenous or oral vitamin D sterol during measurement period CKD Denominators 4.2b1 & 4.2b2 Statement: CKD3-5 (including transplant) beneficiaries with claims for ≥ 90 days supply of oral vitamin D sterol during measurement period Numerator 4.2b1 Statement: : Beneficiaries in the denominator with claims for serum calcium, serum phosphorus, iPTH within 6 months *prior* to initiation of intravenous or oral vitamin D sterol therapy during measurement period Numerator 4.2b2 Statement: Beneficiaries in the denominator with tests for serum calcium, serum phosphorus, (1-84) PTH or iPTH ordered within 6 months *after* initiation of intravenous or oral vitamin D sterol therapy during measurement period

2.6.2. Data Management Preparations

The algorithms in the technical specifications for Measure Set 1 use only Part D enrollment data, Part D drug claims data, and SIMS data. The technical specifications for Measure Set 2 include algorithms that depend on additional data sources, such as administrative claims data that include ICD-9-CM diagnosis codes, CPT procedure codes, and HCPCS drug codes for drugs not covered by Part D.

Part D Enrollment Data: MA-PDs and PDPs submit weekly enrollment data to CMS. Table 12 shows the data elements required from Part D enrollment data for algorithms in Measure Sets 1 and 2. Part D enrollment data are available from CMS and directly from MA-PDs and PDPs.

Table 12. Part D Enrollment Data Elements To Determine Inclusion Eligibility

Field Name (Data Element)	Description
Contract number	Identifies the MA-PD or PDP
PBP number	Plan Benefit Package number CMS assigns to identify a specific benefit within a contract (e.g. standard, enhanced alternative)
HICN/RRB	Health insurance claim number/Railroad Retirement Board number to identify enrollee
SSN	Enrollee social security number
DOB	Date of birth (since DOB is an optional field in Part D data, this field will establish the age of the enrollee)
RxID	This further confirms enrollment of the member as indicated by the ID number on the prescription drug card
Enrollee gender	
PBP Enrollment Effective Date	The effective beginning date of the enrollee's coverage within the PBP
PBP Disenrollment Date	The date that an enrollee disenrolled from a PDP or MA-PD plan; if the date is not available, it may be calculated by checking the monthly enrollment lists
DOD	Date of Death, the date that an enrollee died, if known

Part D PDE Data: MA-PDs and PDPs submit monthly Part D PDE data to CMS. Table 13 shows the Part D drug claim data elements for Measure Sets 1 and 2. Part D claims data are available from CMS and directly from MA-PDs and PDPs.

Table 13. Part D Data Elements for the Measures

Field Name (Data Element)	Description
Contract ID	Identifies the MA-PD or PDP
PBP ID	Plan Benefit Package number CMS assigns to identify a specific benefit within a contract (e.g. standard, enhanced alternative)
HICN	Health insurance claim number identifying the Medicare-eligible beneficiary
Date of Service (DOS)	Date of encounter
Prescription Service Reference No.	Unique prescription number assigned by the pharmacy at the time the prescription is filled
Product Service ID	11-digit National Drug Code (NDC)
Service Provider No	Identifies the dispensing pharmacy
Dispensing Status	Identifies partial fill or complete fill
DAW/Product Selection Code	Indicates the prescriber's instruction regarding substitution of generic equivalents to dispense the specific product written
Quantity Dispensed	Number of units, grams, milliliters, or other units
Days Supply	Duration of therapy
Fill number	Indicates the number fill of the current dispensed supply
Prescriber ID	Identifies the prescriber
Drug Coverage Status	Covered, supplemental, or over the counter (OTC)
Adjustment/deletion	Adjustment to the record

SIMS Data: SIMS provides the most reliable source for identifying the ESRD (hemodialysis and peritoneal dialysis and transplant) population. To identify ESRD patients, each plan's enrollment data are matched to CMS SIMS data according to the technical specifications. ESRD patients identified as having a successful transplant and no dialysis are re-classified to the CKD population. To segregate the transplant patients from the dialysis patients for measurement, the

technical specifications provide a pre-requisite step in data preparation. To gain access to the SIMS data or other data sets to calculate measures in Measure Sets 1 and 2, CMS requires a Data Use Agreement (DUA) executed by the user. Table 14 shows the data elements in SIMS used for identifying ESRD (dialysis and transplant) patients.

Table 14. SIMS Database Elements to Identify ESRD (Dialysis and Transplant) Patients

Field Name (Data Element)	Description
hicnum	Patient health insurance claim number
ssn	Social security number
dob	Patient date of birth
gender	Gender
primdiag	Patient primary ESRD diagnosis
primtrail	Primary ESRD diagnosis trailer
morbidj	Patient diabetes indicator
morbidk	Patient insulin indicator
dialprov	Dialysis provider
dialprovno	Dialysis provider number
faccode	Facility code
dialset	Patient dialysis setting
dialtype	Dialysis type
datebegan	Date dialysis began
datehere	Date patient started at 2728 provider
datestop	Date patient stopped dialysis therapy
datedeath	Date of patient's death
transdate	Date of most recent transplant
transhosp	Transplant hospital
transupin	Transplant hospital provider number
entdate	Date patient entered prep hospital
priorhosp	Transplant prep hospital name
priorprov	Transplant prep hospital provider number
transtatus	Transplant status
dialretdat	Dialysis return date
treatsite	Treatment site
trainname	Training provider name
trainnumbr	Training provider number
traindate	Dialysis training begin date
traintype	Self dialysis training type
traincert	Training completion indicator
trainend	Dialysis training end date
nwcert	Network confirmation indicator
decision	ESRD decision

ICD-9-CM, CPT, and HCPCS Data: ICD-9-CM diagnosis codes are used to identify enrollees with CKD, diabetes, and hypertension for algorithms in Measure Set 2. CPT procedure codes are used to identify monitoring tests used in the measures. HCPCS codes are used to identify drugs used in the measures that are not covered in Part D. For example, HCPCS codes document some drugs such as ESA and paricalcitol that are administered parenterally to ESRD patients during dialysis. ICD-9-CM diagnosis codes are available in CMS Parts A (hospital inpatient), Part B (hospital outpatient and physician) data for PDP enrollees (fee-for-service enrollees), and Part C (hospital inpatient, hospital outpatient, and physician) data for MA-PD managed care enrollees. CPT procedure codes and HCPCS drug codes are documented in Part

B data for PDP enrollees and directly from MA-PDs for managed care enrollees (MA-PDs are not required to submit CPT and HCPCS codes to CMS for managed care enrollees). Table 15 shows the data elements for the measures in Measure Set 2.

Table 15. Data Elements From CMS Parts A, B Data (PDP Enrollees) and From Plan Data (MA-PD Enrollees)

Field Name (Data Element)	Description
HICN	Health Insurance Claim Number
Patient's Name	Last name, first name and middle initial corresponding to the HICN
Patient's birth date (DOB)	MM/DD/CCYY
Patient's Diagnoses/Conditions	ICD-9-CM code number and code to the highest level of specificity for the date of service; use codes in any principal and secondary position
Date of Service (DOS)	6- or 8-digit (MMDDCCYY) date for each diagnosis, procedure, service, or supply
Place of Service	Place of service code, for each item used or service performed
Procedures, services or supplies	Part B or plan data only; procedures, services, or supplies using CPT or HCPCS codes; use codes in any principal and secondary position

In addition to Part D enrollment and drug claims data, SIMS data for Measure Sets 1 and 2, and datasets with ICD-9-CM, CPT, and HCPCS codes for Measure Set 2, both measure sets require access to subscription information from a common drug database supplier such as Medi-Span® or First DataBank® to provide National Drug Codes (NDCs) and drug classification schemes such Medi-Span®'s Generic Product Identifier (GPI) codes. The GPI is a 14-digit code consisting of seven digit pairs. The first pair of digits represents the drug group. Successive paired digits represent the drug class, drug subclass drug name, drug name extension, dosage form, and strength. Typically, eight to ten digits are sufficient to identify commercially available drugs; all 14 digits will specifically identify a drug to its strength and dosage form. The technical specifications and the appendix use the Medi-Span® classification system.

2.6.3. Measurement Period

BearingPoint recommends the measurement period for both Measure Sets 1 and 2 to be 12 months at a minimum, for example, from January 1 through December 31, 2006. If measurement is to be performed on data beginning on January 1, 2006, which marks commencement of the Part D benefits, it should be noted that no data are available from CMS prior to this date that shows what prescriptions each Part D enrollee had filled prior to January 1, 2006 or what drugs they had possession of during the first part of the measurement period. For example, if a beneficiary received a 90-day supply of a phosphate binder in December 2005, then the first claim for continuing phosphate binder therapy under the Part D benefits would not be captured until February or March 2006. Similarly, if a dual eligible enrollee had received Part D covered drugs through Medicaid in the early months of 2006 due to uncertainty of coverage, these drug claims also would not be captured in Part D claims data.

Measure 4.2 in Measure Set 2 may not be calculable even within a measurement period of 12 months. The measurement requires therapeutic monitoring to be performed within six months prior to administration of an active vitamin D sterol *and* within six months post administration

of the drug. Ideally, evidence for therapeutic monitoring would require having all available inpatient/outpatient/physician claims from six months prior to and after a date of service (DOS). So, for example, if a claim for an active vitamin D sterol occurred on January 15, 2006, inpatient/outpatient/physician claims from July 16, 2005 through January 15, 2006, and from January 16, 2006 through July 15, 2006 would be examined for the occurrence of selected therapeutic monitoring tests. If monitoring tests occur more frequently than six months, then the likelihood of capturing the data in a 12-month measurement period would be higher. Ideally, the measurement period would be 12 months for the occurrence of an active vitamin D sterol with the occurrence of therapeutic monitoring during the measurement period or six months prior to the start of the measurement period and six months after the measurement period.

These measures specifications are to test the usability of the data and develop and test the data extraction capabilities of the algorithms, not to estimate accurately or precisely the values of the measures or to compare plans until more is known about the reliability, validity, and adequacy of the data. Data provided directly by Part D sponsors to test these specifications may not have been edited by CMS using CMS data acceptance routines. In addition, the test data may be from the Part D startup period — some data may not be reliable or accurate during this timeframe due to startup difficulties with enrollment and Part D data.

BearingPoint, based on its measure development and testing experiences, recommends that formative testing of Measure Sets 1 and 2 be performed with data from calendar year 2007 or after, at least one year post the debut of Part D, and that measures be based on:

- For Measure Sets 1 and 2, data available from prior to the beginning of the measurement period for measures that require information about prescriptions in possession during the first three months of the measurement period
- For Measure Sets 1 and 2, data from CMS that have been processed through CMS's edit procedures
- For Measure Set 2, increased utilization and validation of the CKD staging ICD-9-CM codes (585.1-585.9), which went into effect in October 2005.

2.6.4. Definitions of CKD/ESRD Populations, Eligibility, and Claims Selection

This section provides an overview of the CKD population, ESRD population, beneficiary eligibility, and claims selection.

ESRD (Dialysis) Population

The ESRD population is defined from the SIMS database, which is used primarily by the ESRD Networks to manage and report patient- and facility-specific information. The ESRD population is defined as patients in the SIMS database who received dialysis at anytime during the measurement period and with no evidence of a functioning transplant. The extract of SIMS data should correspond to the measurement period.

CKD (Including Transplant) Population

For the measures in Measure Set 1, BearingPoint was limited to developing algorithms that used SIMS data to identify CKD beneficiaries with functioning transplants and Part D claims data using drug proxies to identify other Part D enrollees with CKD (ICD-9-CM diagnosis codes are not available in Part D claims data). The drug proxy requires a person to have Part D claims for ≥ 2 fills or a total of ≥ 90 days supply during the measurement period for one of the following drugs: phosphate binder (calcium acetate, sevelamer hydrochloride, lanthanum carbonate), or oral vitamin D sterol (calcitriol, paricalcitol, doxercalciferol, or dihydrotachysterol). This drug proxy, however, only identifies people with later stages of CKD, stages 4 and 5 with some stage 3.

The measures in Measure Set 2, BearingPoint defined CKD using ICD-9-CM codes. The USRDS uses the following ICD-9-CM diagnosis codes to identify CKD patients: 016.0, 095.4, 189.0, 189.9, 223.0, 236.91, 250.4, 271.4, 274.1, 283.11, 403.x1, 404.x2, 404.x3, 440.1, 442.1, 447.3, 572.4, 580–588, 591, 642.1, 646.2, 753.12–753.17, 753.19, 753.2, and 794.4—occurring on at least one hospital inpatient claim or occurring on at least two outpatient hospital or physician claims with different dates of service. This definition can be used for any measure in Measure Set 2 that includes beneficiaries in any stage of CKD (pre-dialysis) such as Measure 3.1; however, it should be noted that people with CKD stages 1 and 2 are underdiagnosed. These codes are not adequate to classify a particular stage of CKD such as used for Measures 3.5, 3.7, 4.1, and 4.2b in Measure Set 2.

In October 2005, new ICD-9-CM diagnosis codes were introduced to classify patients by stage of CKD. The codes are:

- 585.1 CKD Stage 1
- 585.2 CKD Stage 2 (mild)
- 585.3 CKD Stage 3 (moderate)
- 585.4 CKD Stage 4 (severe)
- 585.5 CKD Stage 5 (kidney failure-pre-dialysis)
- 585.6 ESRD (kidney failure and dialysis or transplant)
- 585.9 CKD (unspecified stage).

The reliability, validity, and adequacy of these codes have not been tested. The extent to which these codes were/are actually used in 2006/2007 is unknown. For example, a patient may be diagnosed with 583.81 (nephritis/nephropathy) and this patient may have a GFR of 50 ml/min/1.73m^2, but there is no requirement for the physician to use both 583.81 plus 585.3. There is an expectation that the codes 585.1 through 585.6 will be greatly underused in 2006 and 2007, so that using these codes to identify beneficiaries in 2006 and 2007 by CKD stage may greatly underestimate the actual number of people with the disease. In addition, the extent to which the code for unspecified CKD (ICD-9-CM = 585.9) was used instead of the more appropriate specific ICD-9-CM codes 585.1 through 585.5 in 2006 is expected to change as

physicians become familiar with the staging criteria. Ideally, a separate analysis is required to examine the use of the new ICD-9-CM CKD staging diagnoses to assess the reliability and validity before most measures in Measure Set 2 are calculated.

Due to measure requirements, there are four overlapping CKD populations defined:

- CKD1-5 (used for Measure 3.1 in Measure Set 2) includes beneficiaries who have at least one inpatient hospital claim or at least two outpatient hospital and/or physician claims with an ICD-9-CM diagnosis from the USRDS definition. This group also includes ESRD patients with functioning transplants. There are no drug proxies that define this group.
- CKD1-3 (used for Measure 3.5 in Measure Set 2) includes beneficiaries classified as CKD stages 1, 2, or 3 and includes ESRD patients with functioning transplants. Measure 3.5 is only included in Measure Set 2 because there are no agreed upon drug proxies to identify early stages of CKD.
- CKD3-5 (used for all Measure Set 2 measures except for Measures 3.1, 3.5, and 3.7) includes beneficiaries classified as CKD stages 3-5 (pre-dialysis), ESRD patients with functioning transplants, and unspecified CKD.
- CKD4-5 (used for Measure 3.7 in Measure Set 2) is a subset of CKD3-5 including only beneficiaries classified as CKD Stages 4 or 5 (pre-dialysis) and includes ESRD patients with functioning transplants and unspecified CKD. Measure 3.7 is only in Measure Set 2 because there are no drug proxies to differentiate CKD stage 3 from CKD stages 4 and 5.

2.6.5. Beneficiary Eligibility

There are two steps to determine whether a CKD beneficiary in one of the CKD populations or an ESRD patient in the ESRD population is eligible to be in the denominator for a measure:

Step 1: Include/exclude beneficiaries based on criteria common to all measures. Beneficiaries are eligible if either: 1) they were enrolled in the plan for at least 11 of the 12 months in the measurement period, or 2) they died during the measurement period. It is important to capture the information of beneficiaries/patients who died during the measurement period, especially for patient safety measures, because some of the deaths may be associated with the drugs of interest; if beneficiaries/patients who died are excluded from study, then some measures may be biased. There are two ways to capture the date of death (DOD) for the CKD/ESRD populations. SIMS data from CMS 2746 fields 8, 12a, and 12b document the DOD, primary cause of death, and secondary cause of death, respectively, for ESRD patients (dialysis and transplant). For CKD beneficiaries, DOD should be available in the plan's enrollment data as plans are required to submit enrollment data to CMS on a weekly basis. However, there is usually a time lag between DOD and date of notification. Technically, date of notification should fall within 180 days of the DOD. During the 12-month measurement period, there will inevitably be omissions of deceased beneficiary data due to time lag. It is also important to determine whether beneficiaries who have not died have been continuously enrolled in a drug plan to ensure the completeness of the data. A coverage gap occurs when the beneficiary disenrolls from one plan

and has not signed on with another plan. This is especially relevant to the dual eligible population because benefit status can change with the beneficiary's employment status and because dual eligible beneficiaries can switch plans every 30 days. When beneficiaries have a coverage gap in excess of 30 days, they may be filling prescriptions that are not included in Part D data. Thus, these beneficiaries are excluded since we cannot be sure that we have complete prescription drug information for these individuals.

Step 2: Include/exclude beneficiaries based on criteria unique to each measure. For example, a particular measure may be applicable only to diabetics, hypertensives, or ages 18 or over. These inclusion/exclusion statements are described in the specifications for each measure.

2.6.6. Claims Selection

For the eligible enrollees, Part D claims during the measurement period are selected from Part D covered drugs that have been adjudicated, de-duplicated, and processed through CMS edits. For measures in Measure Set 2, inpatient hospital, outpatient hospital, and physician claims are obtained for ICD-9-CM diagnoses, CPT procedures, and HCPCS drugs not covered by Part D. These also require de-duplicating and examination for anomalies.

2.6.7. Algorithms

The algorithms and the associated drug codes used for Measure Set 1 measures are shown in Appendix L. The algorithms for Measure Set 2 measures and the associated drug codes, diagnosis codes, and procedure codes are shown in Appendix M.

2.6.8. Recommendations

The technical specifications were developed without testing using actual data from Part D enrollment or claims files, or administrative claims files with inpatient, outpatient, or physician data that include diagnosis, procedure, or drug codes. The algorithms and appendix of diagnosis, procedure, and drug codes will require refinement before using in practice and will require maintenance from year to year. The following list is the recommended areas to be refined and maintained.

Refinement
Measure Sets 1 and 2

1. Measurement period
    a. While data from 2006 can be used to test the specifications, BearingPoint recommends that data from 2007 or later be used for actual quality measure calculation for use by QIOs or ESRD Networks.
    b. Part D claims should be available for at least three months prior to the beginning of the measurement period (for measurement periods beginning April 1, 2006 or later due to the commencement of Part D on January 1, 2006) to identify the medications in possession as of the first day of the measurement period.

2. Reliability, validity, and adequacy of SIMS data fields to identify ESRD (dialysis) and ESRD (functioning transplant) patients.
3. Reliability, validity, and adequacy of drug proxies to identify CKD Stages 3 through 5.
4. Completeness of DOD information.
5. Refine process to exclude/include enrollees based on missing data in fields.

Measure Set 2

1. Measurement period

   Inpatient/outpatient/physician claims data should be available for a two-year period—the quality measurement period in addition to six months prior to the beginning and six months after the end of the measurement period for quality measures. This would permit finding the appropriate monitoring tests for measures 4.1 and 4.2. It would also allow more reliable identification of ICD-9-CM codes for enrollees with chronic conditions such as diabetes and hypertension for other measures.
2. Reliability, validity, and adequacy of ICD-9-CM codes (585.1-585.5, 585.9) used to define CKD/ESRD Stages 1-5, and unspecified CKD.
3. Reliability, validity, and adequacy of ICD-9-CM codes to identify ESRD (dialysis) and ESRD (functioning transplant) patients.
4. Refine process to make inpatient, outpatient, and physician data usable—such as deduplicating claims and identifying data anomalies.
5. Refine Measure 3.5—percentage of CKD (Stages 1-3 including transplant) beneficiaries with more than once-a-day dosage regimen of antihypertensive drugs.

Maintenance

Measure Sets 1 and 2

1. For each measurement period, the drug proxies used to define conditions used in the measures need to be updated. The chronic conditions used in these measures are:
   a. CKD
   b. Hypertension
   c. Diabetes.
2. Drugs covered by Part D
3. GPI and NDC Part D drug codes for:
   a. ACEIs
   b. ARBs
   c. Beta blockers
   d. Diuretics

e. Hypertension drugs

f. Oral active vitamin D sterols.

Measure Set 2

1. For each measurement period, the corresponding diagnosis codes used to define conditions used in the measures need to be updated. ICD-9-CM codes are updated once a year in October. The chronic conditions used in these measures are:
   a. CKD
   b. ESRD
   c. Hypertension
   d. Diabetes.
2. For each measurement period, the monitoring tests required for the measures in Measure Set 2 should be reviewed and modified if new tests are introduced or old tests are no longer applicable. For 2006, the measures required procedure codes to define the following monitoring tests:
   a. Complete blood count
   b. Hemoglobin
   c. Hematocrit
   d. Serum ferritin
   e. Iron and total iron binding capacity (TIBC)
   f. Transferrin
   g. Serum calcium (total)
   h. Serum calcium (ionized)
   i. Serum parathyroid hormone (intact/whole molecule)
   j. Serum phosphorus inorganic (phosphate).
3. Drugs not covered by Part D, but covered under Part B. In these measures, as of 2006, Part B covers the following injectable vitamin D sterols:
   a. Paricalcitol
   b. Calcitriol
   c. Doxercalciferol.
4. GPI and NDC Part D drug codes for:
   a. Hypertension daily dosing
   b. ESA.

3. FORMATIVE TESTING

The formative test is the initial usability assessment and refinement of the technical specifications' algorithms for calculating the CKD/ESRD measures using only Part D enrollment and claims data (only Measure Set 1). This section describes the purpose of the formative test, the initial methods used to obtain data from Part D plans, and the criteria used in selecting Part D organizations to participate in the formative testing. However, the Measure Set 1 algorithms were not formative tested or refined.

3.1. PURPOSE

The original scope of work specified for BearingPoint to conduct formative testing of the measures using data provided by the Part D Plans. Yet, given the challenges faced in limiting the data request from plans and difficulties in obtaining plans' data, CMS advised BearingPoint to halt the formative testing. The following sections describe BearingPoint's preliminary efforts in obtaining Part D plans' data.

3.2. METHODS

This section describes the methods used to request data from Part D plans, including the criteria used in selecting Part D organizations to participate and the invitation letter outlining the data specifications.

3.2.1. Methods to Obtain MA-PD and PDP Test Data

CMS required that data used to test measure calculation be obtained directly from at least one Part D plan rather than from CMS because:

- Part D claims data and CMS systems had not matured sufficiently in the first year of data submission
- Extraction of Part D claims data is time-consuming, absent properly defined procedures and specifications for data extraction and data sharing
- CMS did not allow Part D data to be distributed to a contractor other than a QIO.

The process of obtaining data from plans is described below.

3.2.1.1. Criteria for MA-PD and PDP Organization Participation

BearingPoint intended to include Part D plans according to the following criteria:

- A mix of MA-PDs and PDPs
- A mix of new and established (or experienced) plans (MA-PDs that offered drug benefits prior to 2006)

- Large plans that potentially had the highest number of ESRD/CKD enrollees and Special Needs Plans (SNPs) who target ESRD patients and CKD beneficiaries.

Ultimately, the participation of Part D organizations depended upon:

- A plan's willingness and resources to share enrollment and Part D claims data in time to enable BearingPoint to complete the contract activities within CMS's deadlines
- Availability of complete enrollment and Part D claims data for the measurement period, January 1 through December 31, 2006.

3.2.1.2. Introductory Letter

In October 2006, BearingPoint began contacting MA-PDs and PDPs based on total enrollment (within the top 25 MA-PDs and PDPs by enrollment) and contacts within organizations. Appendix N shows a sample invitation email sent to 14 MA-PDs and PDPs between October 2006 and March 2007. An attachment, which was appended to the invitation letter, with the data specifications is also shown. Of the 14 plans that were contacted, most declined to participate or did not respond to emails or phone calls. The most common reason plans cited for declining was limited resources or IT capacity. Some never responded, even after repeated attempts by emails and follow-up phone calls.

Obtaining plans' agreement to participate was challenging for the following reasons:

- Plans' IT resources frequently appeared to be scarce and burdened by demands of enrollment and eligibility verification, which affected prescription drug benefits and the plan's liability, and were prioritized over requests for data sharing.
- The plans' IT departments generally had little capacity to perform data extraction once reporting requirements for Part D began in earnest in August 2006.

By March 2007, one plan agreed to provide BearingPoint with enrollment and Part D claims data to test measure calculation.

3.2.1.3. Plan Data Sharing Agreements

To satisfy the Health Insurance Portability and Accountability Act (HIPAA) requirements, BearingPoint executed a Data Sharing Agreement (DSA) with one participating plan. This effort involved BearingPoint's legal and contract departments and the plan's compliance and legal departments. The principal purposes of the DSAs were to:

- Limit data use to the formative test only. The agreement was to use the data only for this formative test.
- Specify the data required. In an effort to standardize the data format, BearingPoint reiterated the data specifications for enrollment and Part D claims data in the DSA for participating plans.
- Protect confidentiality of the data.

- Define the disposition of the data subsequent to completion of the formative test. For example, the agreements specified whether BearingPoint was to destroy the data or return the data to the provider.
- Describe the contract's provisions to the plan. Upon CMS approval, BearingPoint would provide the calculated measure values for the plan.

3.2.2. Methods to Extract Data and Calculate Measures

3.2.2.1. Data File Structure

BearingPoint suggested requesting ESRD data in steps so that: 1) The plan would send the Part D enrollment file with only HICN (patient identifier) information for BearingPoint to match the enrollment file with HICNs in the SIMS data to identify ESRD patients, and 2) BearingPoint would send the plan the list of ESRD enrollees for whom the plan would extract Part D claims for BearingPoint. For the CKD population, BearingPoint sent the plan the drug proxy algorithm, allowing the plan to select the CKD enrollees and their Part D claims.

The plan was asked to select only paid/non-reversed Part D claims with fill dates from January 1 through December 31, 2006. The plan would not send BearingPoint PDE data in the format that they send to CMS because only limited fields were required. For this project, therefore, the claims data are referred to as Part D claims, not PDE data. The plan was asked to populate the following fields:

- Member ID Number (the same masked Member ID used in the enrollment file)
- Drug NDC code
- Drug name
- Drug GPI
- Drug route of administration
- Drug dosage form
- Drug strength
- Claim date of service
- Claim drug metric quantity dispensed
- Claim drug days supply
- Claim prescription number
- Part D coverage status code (C-covered, E-extended, O-over-the-counter)
- Quantity dispensed.

3.2.2.2. Data Standardization

To prepare the data for loading into calculation programs, BearingPoint planned to standardize the plans' enrollment and Part D claims files. The data files were to be formatted uniformly, separated into an enrollment file and a claims file, and all files were to be de-duplicated, and the deleted claims reversed.

3.2.3. Methods to Modify Technical Specifications

BearingPoint expects that modifications to the technical specifications will result from the formative test. Further testing is required to determine:

- Reliability and validity of using drug proxies to define CKD
- Expansion/revision of data cleaning procedures
- Completeness of date of death information with an appropriate lag time to capture DOD.

3.3. SUMMARY OF DATA CHALLENGES

Obtaining data directly from plans instead of directly from CMS will most likely pose challenges when formative testing of any measure proceeds. Variances in data format, data extraction procedures, and timing of data extraction (PDE claim processing is dynamic and the data can change daily depending on the cutoff date for data extraction) could impact data integrity and add processing time for code revision when the data fields and format are not standardized. Only CMS data can be obtained in a uniform configuration. BearingPoint requested that plans provide Part D data already validated by CMS, e.g., elimination of non-Part D drugs, invalid HICN, invalid DOB, or invalid NDC for a drug covered under Part B. It was not feasible within this contract's scope of work to ascertain if the files provided would be free of errors, as defined by CMS. Table 16 shows a sample list of errors in CMS's edits that are important to be applied to data received directly from plans.

Table 16. Sample List of Errors Not Checked in Data

Dispensing status is invalid
Quantity dispensed is invalid
Days supply is invalid
Drug coverage status code is missing or invalid
Adjustment code is invalid
Adjustment/deletion prescription drug event (PDE) record does not match existing PDE record
Value of dispensing status on adjustment record and the record to be adjusted must be the same
Health insurance claim number (HICN) does not match an existing beneficiary
Date of birth (DOB) provided does not match DOB in Medicare Beneficiary Database (MBD)
Gender does not match value on MBD
Date of Service (DOS) is after date of death
Beneficiary is not enrolled in this Part D plan benefit package on the DOS
DOS is before national drug code (NDC) effective date
NDC is for a drug usually covered under Part B
NDC is DESI drug

Table 16. Sample List of Errors Not Checked in Data
Incompatible dispensing status
Incompatible dispensing status
Record had no error but was submitted as part of a rejected file. Drug Data Processing System rejects file with error rates exceeding 50%

4. MEASURE MANAGEMENT SYSTEM ADHERENCE

CMS worked with a contractor, Health Services Advisory Group (HSAG), to develop a Measure Management System (MMS) that assists the agency in the maintenance of its quality measures across all settings. Per the contract's SOW, BearingPoint was required to:

- Adhere to the measure development process outlined within the MMS blueprint
- Keep the measure manager contractor informed about the progress of the measure development activities
- Complete the MMS measure forms prior to completion of the project.

BearingPoint collaborated with HSAG to implement the measure manager process. The team used and adhered to the MMS protocols while developing the measures and, when appropriate, provided feedback to HSAG for suggested refinements to these protocols.

Following CMS approval of the measures' technical specifications, BearingPoint completed the MMS forms for each of the measures in Measure Set 1. Per HSAG's advice, the team combined some measures when completing the forms. Specifically, the team combined:

- Both DDI measures for ESRD in one form, explaining that one denominator is a subset of the other and that the numerators are the same
- Both DDI measures for CKD in one form, explaining that one denominator is a subset of the other and that the numerators are the same
- Absolute and Adjusted Generic Utilization Ratios measures for ESRD in one form, explaining the relationship between the two ratios
- Absolute and Adjusted Generic Utilization Rations measures for CKD in one form, explaining the relationship of between the two ratios
- Both Part D Drug measures for ESRD in one form, explaining that one denominator is a subset of the other and that the numerators are the same
- Both Part D Drug measures for CKD in one form, explaining that one denominator is a subset of the other and that the numerators are the same.

The MMS forms are described below.

- Measure Information Form. Provides detailed descriptive information for each measure, including, but not limited to:
  - General characteristics—measure name, description, CMS contact, consumer care need, quality domain, type of measure, and body system
  - Variable characteristics—care setting, unit of measure, and endorsement status

- Technical specifications—target population, anchor date, effective date, numerator and denominator statements, exclusion criteria, and data sources
- History—measure status, developer, intellectual property status, development start date, and CMS implementation use.

• Measure Justification Form. Provides information related to each measure's:

- Importance/relevance—for example, epidemiological relevance, financial relevance, policy relevance
- Scientific soundness—for example, evidence base, literature citations for clinical guidelines, and literature citations for supporting evidence/study
- Usability/actionability—for example, provide actionable decision support, clear message to recipient, operational relevance
- Feasibility—for example, specifications are well-defined, reasonable burden of data collection, minimum distortion.

5. SUMMARY

Concurrent with the implementation of the Part D benefit, CMS, BearingPoint, and a technical expert panel succeeded in developing an initial set of medication measures that QIOs and ESRD Networks could choose to test and develop further to assist PDPs and MA-PDs in identifying potential areas of quality improvement for this special population. This initial set of ESRD/CKD medication measures covers common drug safety concerns, such as potential drug-drug interactions, drugs requiring appropriate dosing, and drugs to be avoided. It covers use of the Part D benefit by both ESRD and CKD populations. It covers a common concern for the diabetic CKD population: the use of ARBs and ACEIs to regulate blood pressure. It covers bisphosphonate therapy, potassium-sparing diuretic therapy, and antihypertensive therapy in the CKD population.

With availability of additional data such as ICD-9-CM diagnosis codes, CPT procedure codes for therapeutic monitoring, and HCPCS codes for drugs not covered by Part D, measures were developed to examine the use of more than once-per-day antihypertensive drugs, the use of thiazides without loop diuretics, anemia evaluation in patients treated with ESA, and vitamin D sterol therapy monitoring. Table 17 shows a summary of the developmental stages of the measures.

The measure algorithms were developed with certain constraints imposed:

- Only enrollment, limited Part D data fields, and SIMS data could be used in the Measure Set 1 algorithms
  - Drug proxies, rather than diagnosis codes, were used to define the disease states of diabetes and CKD.
  - Measures in Measure Set 1 could not include important disease-specific therapy or therapeutic monitoring measures, such as anemia evaluation or vitamin D sterol therapy monitoring, because additional data such as ICD-9-CM diagnosis codes, CPT procedure codes, and HCPCS drug codes for drugs not covered by Part D were necessary in algorithms. Algorithms using these additional data sources were developed in the Measure Set 2 Technical Specifications because the TEP indicated that these measures were important to further develop.
- Algorithms were developed without formative testing with actual data
  - Algorithms were developed based on assumptions and experience, not actual evidence of the quality of actual enrollment and Part D data; algorithms may be simplified if certain data fields prove to be complete, reliable, and valid.
  - All algorithms need to be reviewed and refined when the quality of the enrollment and Part D fields is known. This includes the eligibility of enrollees to be included in each measure.
  - Algorithms need to be refined after testing the identification of ESRD dialysis and transplant enrollees using the SIMS database.

- Algorithms may be simplified by using ICD-9-CM diagnosis codes to identify Part D enrollees with CKD by the stage of disease only after the reliability and validity of the ICD-9-CM diagnosis codes has been established.

These measures should be further refined based on complete, comprehensive, and mature Part D enrollment and claims data. To identify most disease states or to adjust for risk, data with ICD-9-CM codes for the population examined are necessary. Access to diagnosis codes would most certainly necessitate integrating data from many sources Prior to each calculation of the measures, it is also important to update the drug codes for each of the measures, the appropriateness of therapies to accommodate changes in best practices, and the ICD-9-CM, CPT, and HCPCS codes used in Measure Set 2. Periodic revision of the drugs included in the drug-drug interaction list as well as the drugs requiring appropriate dosing and drugs to avoid is advisable. Also, the list of drugs covered by Part D needs periodic updating.

Table 17. Development Summary of the Proposed ESRD/CKD Quality Measures

First List of Candidate Measures	First TEP	Stakeholders Website	Stakeholders Meeting and Second TEP	Final List of Measures
Measure Set 1. Quality Measures Using Only Part D Enrollment, Data, Part D Claims Data, and SIMS Data				
Patient Safety Measures – Drug-Drug Interaction (DDI)				
Prevalence of the number of Chronic Kidney Disease (CKD) beneficiaries and/or End Stage Renal Disease (ESRD) patients who had two or more Prescription Drug Event (PDE) claims for drugs with the potential to interact	Percentage of CKD beneficiaries and ESRD patients who had two or more drugs with the potential to interact	Modified and split into two measures reporting CKD and ESRD separately 1.1a - Percentage of ESRD (dialysis) patients who had ≥ 2 drugs with the potential to interact 1.1b - Percentage of all CKD (including transplant) beneficiaries who had ≥ 2 drugs with the potential to interact	Modified and split into four measures. For each population, two separate denominators: 1. CKD/ESRD 2. CKD/ESRD with ≥ 1 drug on DDI list	**1.1a1 - Percentage of ESRD (dialysis) patients with ≥ 2 drugs with the potential to interact** **1.1a2 - Among ESRD (dialysis) patients with ≥ 1 object or precipitant drug, percentage with ≥ 2 drugs having the potential to interact** **1.1b1 - Percentage of CKD (including transplant) beneficiaries with≥ 2 drugs with the potential to interact** **1.1b2 - Among CKD (including transplant) beneficiaries with ≥ 1 object or precipitant drug, percentage with ≥ 2 drugs having the potential to interact**
Patient Safety Measures – Drugs Requiring Caution/Appropriate Dosing/Drugs To Avoid				
Prevalence of Drugs to Avoid (DTA) in CKD beneficiaries and/or ESRD patients	ESRD: Modified Percentage of ESRD (dialysis) patients with Drugs Requiring Caution (DRC) CKD: Deleted		Modified and revised name	**1.2a - Percentage of ESRD patients with drugs to be avoided**
Appropriate dosing of selected drugs among CKD beneficiaries and/or ESRD patients	Percentage of CKD (stages 3, 4, and 5 pre-dialysis) beneficiaries with Drugs Requiring Caution (DRC)		Modified and revised name	**1.2b-Percentage of CKD (including transplant) beneficiaries with drugs requiring appropriate dosing**
Appropriate dosing of erythropoietin (EPO) among CKD beneficiaries and/or ESRD patients	Deleted			
Prevalence of iron supplement among CKD beneficiaries and/or ESRD patients	Deleted			

Table 17. Development Summary of the Proposed ESRD/CKD Quality Measures (cont'd)				
First List of Candidate Measures	**First TEP**	**Stakeholders Website**	**Stakeholders Meeting and Second TEP**	**Final List of Measures**
Measure Set 1. Quality Measures Using Only Part D Enrollment, Data, Part D Claims Data, and SIMS Data				
Pharmacoeconomic Measures				
Prevalence of generic utilization ratio among PDE claims for CKD beneficiaries and/or ESRD patients	Generic utilization ratio among drug claims for ESRD (dialysis) patients	Modified and rephrased referring to absolute and adjusted ratios		**2.1a - Percentage of generic utilization (absolute) for ESRD (dialysis) patients** **2.2a - Percentage of generic utilization (adjusted) for ESRD (dialysis) patients**
	Generic utilization ratio among drug claims for CKD (3, 4, and 5 pre-dialysis) beneficiaries	Modified and rephrased referring to absolute and adjusted ratios		**2.1b - Percentage of generic utilization (absolute) for CKD (including transplant) beneficiaries.** **2.2b - Percentage of generic utilization (adjusted) for CKD (including transplant) beneficiaries**
Disease Specific Therapy Measures – CKD Diabetes Mellitus and ACEI/ARB Therapy				
	Percentage of CKD beneficiaries with diabetes mellitus (DM) on chronic ACEIs and/or ARBs therapy	Percentage of CKD beneficiaries with diabetes mellitus (DM) at least 1 claim for ACEI and/or ARB drugs	Modified given that the definition of chronic or persistent therapy is not limited to 180 days (90 is consider sufficient)	**3.1 - Percentage of CKD (including transplant) beneficiaries with diabetes mellitus (DM) with ≥90 days supply of ACEI and/or ARB drugs**
Disease Specific Therapy Measures – CKD and Bisphosphonate Therapy				
Prevalence of PDE claims for bisphosphonates among CKD beneficiaries and/or ESRD patients	ESRD: Deleted CKD: Modified Percentage of CKD beneficiaries (3 to 5, pre-dialysis) with claims for bisphosphonates who had been tested for serum PTH	Modified measurement period for PTH. Moved to Measure Set 2	Re-phrased to exclude PTH so that it can be calculated with Part D data. Moved back to Measure Set 1	**3.2 - Percentage of CKD (including transplant) beneficiaries with ≥90 days supply of bisphosphonates**

Table 17. Development Summary of the Proposed ESRD/CKD Quality Measures (cont'd)				
First List of Candidate Measures	**First TEP**	**Stakeholders Website**	**Stakeholders Meeting and Second TEP**	**Final List of Measures**
Measure Set 1. Quality Measures Using Only Part D Enrollment, Data, Part D Claims Data, and SIMS Data				
Disease Specific Therapy Measures – CKD/ESRD and Part D Drugs				
	ESRD (dialysis) patients with ≤1 Part D covered drug in claims	ESRD (dialysis) patients with at least one Part D covered drug in claims	Modified and split into two measures to show patients who have no claims	**3.3a1-Percentage of ESRD (dialysis) patients with ≥1 Part D claim** **3.3a2-Percentage of ESRD (dialysis) patients with no Part D claims**
	CKD (3, 4 and 5 pre-dialysis) beneficiaries with ≤1 Part D covered drug in claims	CKD (3, 4 and 5 pre-dialysis) beneficiaries with at least one Part D covered drug in claims	Modified and split into two measures to show patients who have no claims	**3.3b1-Percentage of CKD (including transplant) with ≥1 Part D (other than proxy drugs used to define CKD) claim** **3.3b2 - Percentage of CKD (including transplant) beneficiaries with no Part D claims (other than proxy drugs used to define CKD)**
Disease Specific Therapy Measures – CKD and Antihypertensive Therapy				
	Percentage of CKD (3, 4 and 5 pre-dialysis) beneficiaries and kidney transplant patients with claims for antihypertensive therapy		Modified and rephrased to show CKD and transplant patients combined in the denominator population	**3.4 - Percentage of CKD (including transplant) beneficiaries with ≥ 90 days supply of antihypertensive therapy (excluding potassium-sparing diuretics)**
Prevalence of zero antihypertensive agents among CKD beneficiaries and/or ESRD patients	Deleted			
Prevalence of monotherapy in hypertensive treatment among CKD beneficiaries and/or ESRD patients	Deleted			
Prevalence of using ≥2 antihypertensive agent among CKD beneficiaries and/or ESRD patients	Deleted			

Table 17. Development Summary of the Proposed ESRD/CKD Quality Measures (cont'd)

First List of Candidate Measures	First TEP	Stakeholders Website	Stakeholders Meeting and Second TEP	Final List of Measures
Measure Set 1. Quality Measures Using Only Part D Enrollment, Data, Part D Claims Data, and SIMS Data				
Disease Specific Therapy Measures – CKD and Potassium-Sparing Diuretic Therapy				
	Percentage of CKD 4 beneficiaries and kidney transplant patients with claims for potassium-sparing diuretics	Divided into two measures reporting CKD and kidney transplant patients separately	Modified and rephrased to show CKD and transplant patients combined in the denominator population	**3.6 - Percentage of CKD (including transplant) beneficiaries with ≥90 days supply of potassium-sparing diuretics**
Disease Specific Therapy Measures – Others				
	Percentage of claims for calcitriol, doxercalciferol, or paricalcitol among CKD beneficiaries (stages 4 to 5, pre- dialysis) and ESRD (dialysis) patients	Modified denominators and numerators to exclude the pediatric population. Divided into two measures reporting CKD and ESRD populations separately	Deleted	
	Percentage of CKD (3, 4 and 5 pre-dialysis) beneficiaries and transplant patients with hypertension (HTN) on ACEI/ARB	Modified and split into two measures reporting CKD and kidney transplant patients separately	Deleted	
Prevalence of PDE claims for oral calcitriol, doxercalciferol or paricalcitol among CKD beneficiaries and/or ESRD patients	Modified	Modified and split into two measures reporting CKD and kidney transplant patients separately	Deleted	
Prevalence of lipid lowering drugs (statins or fibrates) among CKD beneficiaries and/or ESRD patients	ESRD: Deleted CKD: Modified Percentage of CKD beneficiaries and ESRD (dialysis) patients with lipid lowering drugs (LLDs) (statins or fibrates) in claims	Modified and split into four measures to report ESRD and CKD populations separately	Deleted	
Prevalence of combined use of HMG CoA Reductase Inhibitors (or statins) and fibrates among CKD beneficiaries and /or ESRD patients	Deleted			

Table 17. Development Summary of the Proposed ESRD/CKD Quality Measures (cont'd)				
First List of Candidate Measures	**First TEP**	**Stakeholders Website**	**Stakeholders Meeting and Second TEP**	**Final List of Measures**
Measure Set 1. Quality Measures Using Only Part D Enrollment, Data, Part D Claims Data, and SIMS Data				
Therapeutic Monitoring Measures				
	Therapeutic Monitoring for CKD (3, 4 and 5 pre-dialysis) beneficiaries and ESRD patients on iron supplement	Percentage of ESRD patients on iron supplement who had therapeutic monitoring	Deleted	
Prevalence of CKD beneficiaries and/or ESRD patients potentially eligible for enrollment in medication therapy management program (MTMP)	Deleted			

Table 17. Development Summary of the Proposed ESRD/CKD Quality Measures (cont'd)				
First List of Candidate Measures	**First TEP**	**Stakeholders Website**	**Stakeholders Meeting and Second TEP**	**Final List of Measures**
Measure Set 2. Quality Measures Using Part D, SIMS, and Additional Data				
CKD Diabetes Mellitus and ACEI/ARB Therapy (using ICD-9-CM codes to identify CKD and diabetes)				
				3.1 - Percentage of CKD (Stages 1-5 including transplant) beneficiaries with diabetes mellitus (DM) and hypertension (HTN) with ≥90 days supply of ACEI and/or ARB drugs *
Disease Specific Therapy – CKD and Antihypertensive Therapy				
	Percentage of CKD beneficiaries (3 to 5, pre-dialysis) and transplant patients with HTN on > once-a-day dosage regimen of antihypertensive drug	Modified and split into two measures reporting CKD and kidney transplant patients separately	Modified and rephrased to report only for the CKD population. Reclassified to Measure Set 2.	**3.5 - Percentage of CKD (Stages 1-3 including transplant) beneficiaries with more than once-a-day dosage of antihypertensive drugs**
Disease Specific Therapy – CKD and Thiazide Therapy				
Percentage of CKD (4 and 5 pre-dialysis) beneficiaries, ESRD (dialysis) and transplant patients with claims for thiazide diuretics		Modified name and split into two measures reporting CKD and ESRD populations separately	ESRD: Delete CKD: Deferred to Measure Set 2	**3.7 - Percentage of CKD (Stages 4-5 including transplant) beneficiaries with ≥ 90 days supply of thiazide diuretics, but no loop diuretics**
Therapeutic Monitoring – CKD and Anemia Evaluation				
Prevalence of therapeutic monitoring among CKD beneficiaries and/or ESRD patients who had PDE claims for epoetin or darbepoetin	CKD: Therapeutic Monitoring for CKD (3, 4 and 5 pre-dialysis) beneficiaries and ESRD patients with epoetin (EPO) and its analogue in claims	CKD: Modified name to exclude ESRD ESRD: Deleted		**4.1 - Percentage of CKD (Stages 3-5 including transplant) beneficiaries with an anemia evaluation prior to treatment with erythropoiesis stimulating agents (ESA)**
Prevalence of epoetin or darbepoetin among CKD beneficiaries and/or ESRD patients	Deleted			

** Measure 3.1 is also included in Measure Set 1 because the original definition used drug proxies to identify CKD and diabetes. This measure was further refined using ICD-9-CM codes to identify diabetic hypertensive CKD (Stages 1-5) beneficiaries.

Table 17. Development Summary of the Proposed ESRD/CKD Quality Measures (cont'd)				
First List of Candidate Measures	**First TEP**	**Stakeholders Website**	**Stakeholders Meeting and Second TEP**	**Final List of Measures**
Measure Set 2. Quality Measures Using SIMS, Part D, and Additional Data				
Therapeutic Monitoring – CKD/ESRD and Vitamin D Sterol Therapy Monitoring				
	Therapeutic monitoring of active vitamin D sterol therapy among CKD (3, 4 and 5) beneficiaries and ESRD patients	Modified and split into four measures, reporting CKD and ESRD populations separately	Deferred to Measure Set 2	**4.2a1- Percentage of ESRD (dialysis) patients on vitamin D sterol therapy with therapeutic monitoring within 6 months prior to initial vitamin D sterol therapy** **4.2a2 - Percentage of ESRD (dialysis) patients on vitamin D sterol therapy with therapeutic monitoring within 6 months after initial vitamin D sterol therapy** **4.2b1 - Percentage of CKD (Stages 3-5 including transplant) beneficiaries on vitamin D sterol therapy with therapeutic monitoring within 6 months prior to initial vitamin D sterol therapy** **4.2b2 - Percentage of CKD (Stages 3-5 including transplant) beneficiaries on vitamin D sterol therapy with therapeutic monitoring within 6 months after initial vitamin D sterol therapy**

6. APPENDICES